Siebel

Clinical Trial Management System Guide

July 2020

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Authors: Siebel Information Development Team

Contents

Preface

This preface introduces information sources that can help you use the application and this guide.

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1 What's New in This Release

What's New in Siebel Clinical Trial Management System Guide, Siebel CRM 20.7 Update

The following information lists the changes in this revision of the documentation to support this release of the software.

Topic	Description
Siebel Clinical Task-Based UI	New chapter. Describes the task-based user interface for Siebel Clinical, which clinical research associates (CRAs) use to manage protocols, regions, and sites for clinical studies.
Supporting Blinded and Unblinded Users for Clinical Trials	New chapter. Describes blinded and unblinded support in Siebel Clinical, how to control access to data for blinded and unblinded users, and how to administer blinded and unblinded users for clinical trials.

What's New in Siebel Clinical Trial Management System Guide, Siebel CRM 20.1 Update

No new features have been added to this guide for this release. This guide has been updated to reflect only product name changes.

What's New in Siebel Clinical Trial Management System Guide, Siebel CRM 19.7 Update

The following information lists the changes in this revision of the documentation to support this release of the software.

Topic	Description
Creating Questions for Clinical Trip Reports Using Siebel SmartScript *Completing Questionnaires for Clinical Trip Reports*	Modified topics. The ability to add comments against questions in Siebel SmartScript is supported in Siebel CRM 19.7 Update and later releases.

What's New in Siebel Clinical Trial Management System Guide, Siebel CRM 19.1 Update

No new features have been added to this guide for this release. This guide has been updated to reflect only product name changes.

2 Overview of Siebel Clinical Trial Management System

Overview of Siebel Clinical Trial Management System

This chapter provides an overview of Oracle's Siebel Clinical Trial Management System. It includes the following topics:

- *About Siebel Clinical Trial Management System*
- *Features of Siebel Clinical Trial Management System*
- *Product Modules and Options for Siebel Clinical Trial System*

About Siebel Clinical Trial Management System

Siebel Clinical Trial Managements System allows biotechnology companies, pharmaceutical companies, and CROs (clinical research organizations) to better manage the clinical trial process, maintain quality of clinical trials, and manage investigator relationships. It provides a comprehensive set of tools for CRAs (clinical research associates), clinical investigators, and site coordinators, and includes a personalized Internet portal to conduct study activities more efficiently.

The following products are supported:

- Siebel Clinical Trial Management System
- Siebel Clinical Trial Management System Cloud Service

Features of Siebel Clinical Trial Management System

Siebel Clinical supports the following functionality:

- Support for full clinical trial hierarchies of Subject-Site-Region-Protocol-Program
- Support for global trials running in multiple countries, multiple languages, and multiple currencies
- Support for randomized trials
- Support for multi-arm, epoch, and adaptive trials
- Site management tools for CRAs (clinical research associates), including a site calendar, trip reports, document tracking, and payment generation
- Personalized Internet portal to help site coordinators, clinical investigators, and CRAs better manage clinical trials over the Web
- Project and resource management
- A flexible audit trail engine

- Investigator and site profiling
- Activity and calendar management for CRAs and clinical sites
- Clinical trial status and management reports for study manager and CRAs
- Integrated payment tracking for sites and investigators
- Support for multiple accounts associated with a clinical protocol
- Support for multiple contracts associated with a clinical site
- Subject visit templates for study staff to better plan subject visits and promote protocol adherence
- Automatic tracking of subject status on completion of relevant visits, eliminating manual errors.
- Clinical trip report templates for CRAs to facilitate compliance with good clinical practice (GCP)
- Automated notification emails sent to the owner, reviewer, and approver of the trip reports
- Audit trail for reviews and approvals of trip reports
- Approver verification of clinical trip reports
- Support for the Siebel Open UI framework
- Siebel Clinical Trial Management System Cloud Service for Software as a Service (SaaS) deployments
- Clinical operations integration for budget planning and tracking
- Source data verification to ensure that data collected during clinical trials is complete, accurate, and verifiable
- Support for planning and tracking of clinical training

Siebel Clinical is designed to allow CROs (clinical research organizations), pharmaceutical and biotech companies, and other clinical trial sponsors to:

- Deploy a Web-based clinical trial management system to internal and external users.
- Make better decisions throughout the clinical trials process, leading to more efficient use of resources and faster time to market.
- Increase productivity of CRAs and their managers by automating repetitive tasks and allowing real-time information sharing.
- Create sustainable competitive advantage by allowing customers to provide breakthrough service to sites and investigators.
- Provide a solution integrated with Siebel Pharma Sales and Siebel Pharma Service to allow customers to deploy one customer management solution across the entire enterprise.

Siebel Clinical supports the 21 CFR Part 11 industry standard.

Product Modules and Options for Siebel Clinical Trial System

You can purchase many Siebel Business Applications modules and use them with Siebel Clinical Trial Management System and Siebel Life Sciences. In addition, you can purchase the optional modules that are specific to Siebel Life Sciences to provide enhanced functionality for various business processes. For information about the optional modules to use with Siebel Life Sciences and Siebel Clinical Trial Management System, contact your Oracle sales representative.

This guide documents Siebel Life Sciences with the optional modules installed. In addition, the Sample database includes data for optional modules. If your installation does not include some of these modules, then your software interface differs from that described in some sections of this guide.

The exact configuration of Siebel Life Sciences screens and views depends on your company's configuration of Siebel Life Sciences. For more information about Siebel Life Sciences, see *Siebel Life Sciences Guide* .

For introductory information about using the Siebel Life Sciences interface, see *Siebel Fundamentals* .

Note: The *Siebel Bookshelf* is available on Oracle Technology Network (http://www.oracle.com/technetwork/indexes/documentation/index.html) and Oracle Software Delivery Cloud. It might also be installed locally on your intranet or on a network location.

3 Setting Up Siebel Clinical

Setting Up Siebel Clinical

This chapter covers setting up Siebel Clinical. It includes the following topics:

About Setting Up Siebel Clinical

This chapter lists the administrative tasks that are specific to Siebel Clinical. Use this chapter in combination with the main guide for performing administrative tasks, *Siebel Applications Administration Guide* .

Siebel Applications Administration Guide covers the setup tasks that are common to all Siebel Business Applications, such as using license keys, defining employees, and defining your company's structure. It also provides the information that you need to implement, configure, and monitor the Sales, Service, and Marketing products and to perform Data Administration and Document Administration tasks.

Some tasks listed in this chapter might replace tasks in *Siebel Applications Administration Guide* . Other tasks might be additional tasks. Make sure you review *Administrative Setup Tasks for Siebel Clinical* before following the procedures in *Siebel Applications Administration Guide* .

This guide assumes that you already installed Siebel Clinical or completed an upgrade from another Siebel Business Application. If you have not, then refer to the Installation/Upgrade section of the *Siebel Bookshelf* , and click the links to the guides that are relevant to your company's implementation.

The Siebel database server installation script creates a Siebel administrator account that you can to perform the tasks described in this guide. For information about this process, see the *Siebel Installation Guide* for the operating system you are using and *Siebel System Administration Guide* .

> **Note:** Do not perform system administration functions on your local database, as these functions can cause data conflicts, an overly large local database, or a large number of additional transactions to route.

Configuring Properties for Siebel Clinical in Siebel Tools

User properties are object definitions that are added to an applet, business component, control, field, or list column to enable and configure specialized behavior. User properties drive some Siebel Clinical features. You can customize these features through their respective user properties. With user properties, you can control behavior in the user interface, change default settings or leave them as they are, and enable or disable features. For information about enabling and configuring the Siebel Tools object definitions required for Siebel Clinical, see *Developer's Reference for Siebel Clinical*.

Enabling or Disabling Siebel Open UI for Siebel Clinical

To enable or disable Siebel Open UI for Siebel Clinical, you must configure the EnableOpenUI parameter for the eClinicalObjMgr_enu Object Manager. Siebel Open UI is disabled by default. For information about configuring the Object Manager to enable Siebel Open UI, see the *Siebel Installation Guide for the operating system you are using* .

Enabling Siebel Server Component Groups for Siebel Clinical

This system administration task describes how to activate the component groups that are required for Siebel Clinical.

To enable Siebel Server component groups for Siebel Clinical

1. Navigate to the Administration - Server Configuration screen, then the Component Groups view.
2. Complete the following steps to set the component groups:
    a. Query for the Workflow Management Component Group.
    b. On the Component Groups applet, click Enable.
    c. Query for the EAI Component Group.
    d. On the Component Groups applet, click Enable.
3. Navigate to the Administration – Server Management screen, then the Servers and Component Groups view.
4. Verify that the State value for the Workflow Management and EAI Component Groups is set to Online.
5. Navigate to Administration – Server Configuration screen, then the Enterprises and Synchronize view.
6. Click Synchronize.
7. Restart the Siebel Server.

Activating Workflow Policies for Siebel Clinical

This system administration task describes how to activate the workflows and workflow policies required for Siebel Clinical. *Workflows in Siebel Clinical* shows a list of workflows for Siebel Clinical.

To activate the workflow policies for Siebel Clinical

1. Navigate to the Administration - Business Process screen, then the Workflow Deployment view, and perform the following steps:
   a. Query for all the workflows using the following criteria, and activate the workflows:
      - `*Clinical*`
      - `SWI - Protocol*`
   b. Verify that each activated workflow is added to the Active Workflow Processes list view at the end of the screen.
2. Navigate to the Administration - Runtime Events screen, click Menu (the cogwheel icon), and select Reload Runtime Events.
3. Navigate to the Administration - Business Process screen, then the Workflow Policies view, and perform the following steps:
   a. Query workflow policies for `LS Clinical*`
   b. Set the activation date to one day before today's date for all policies.
   c. Check that expiration date is NULL for all policies.
4. Navigate to the Administration - Server Management screen, then the Jobs view, and perform the following steps to generate triggers for the workflow policies returned from your query:
   a. Define a job for Generate Triggers component with the following parameters:
      - EXEC: True
      - Mode: ALL
      - Privileged User: `<%SADMIN%>`
      - Privileged User Password: `<%PASSWORD%>`
   b. Start the job and query until the status is Success.
5. From the srvrmgr command utility, perform the following steps:
   a. Create a component definition for the LS Clinical Rollup policy group as follows:
      - Component definition: LSCLIN
      - Component type: WorkMon
      - Component group: Workflow
      - Run mode: Background
      - Full name: LS Clinical
      - Description: Monitors LS Clinical Workflow Manager events
      - Parameter DfltTasks=1, GroupName=LS Clinical Rollup, SleepTime=30

      > **Note:** When working with component definition commands, launch and run the srvrmgr program for the enterprise; that is, do not start srvrmgr with the back slash s (`/s`) (or `-s` for UNIX).

      The component alias must be unique across the enterprise, and must not be more than 30 characters in length. Also be careful not to use keywords in the component description, such as *for* or *component*, unless the words are enclosed in quotes.

      The component definition command starts a task to perform actions on LS Clinical Rollup group policy as a result of updates on the corresponding tables that the database triggers monitor.

The SleepTime parameter represents the time in seconds for processing requests. The default value is 20 seconds. Setting the SleepTime parameter to a low value or zero can have serious negative performance consequences.

b. Enter the following command to enable the LS Clinical Rollup component:

```
enable component definition LSCLIN
```

6. Navigate to the Administration - Server Configuration screen, then the Synchronize view, and perform the following steps:

   a. Click Synchronize.
   b. Verify that the Workflow Monitor Agent is running.

   If it is not activated, then start the Workflow Monitor Agent task again.

7. Navigate to the Administration - Server Management screen, then the Tasks view, and perform the following steps to set the action interval for the Workflow Monitor Agent task:

   a. Navigate to the Parameters view.
   b. In the Tasks list, query for the Workflow Monitor Agent in the Component field.
   c. In the Task Parameters list, query for Action Interval in the Parameter field and set the value to 10.

Configuring Web Services for Siebel Clinical

This task describes how to configure Web services for Siebel Clinical. For more information about configuring Web services, see *Integration Platform Technologies: Siebel Enterprise Application Integration* .

> **Note:** It is recommended that you use HTTPS authentication. For information about configuring Secure Sockets Layer (SSL) for HTTPS authentication, see *Siebel Security Guide* .

To configure Web services for Siebel Clinical

1. Navigate to the Administration - Web Services screen, then the Inbound Web Services view.
2. Query for the ClinicalSubject Inbound Web service.
3. On the Service Ports applet, update the Address variable to point to your Web server, and configure the Language variable.
4. Query for the SWILSClinicalQueryProtocolSite_SiteVisits Web service.
5. On the Service Ports applet, update the Address variable to point to your Web server, and configure the Language variable.
6. Query for the SWILSClinicalCreateSiteVisitGeoLocation Web service.
7. On the Service Ports applet, update the Address variable to point to your Web server, and configure the Language variable.
8. Click Clear Cache on the Inbound Web Services applet.

Administrative Setup Tasks for Siebel Clinical

The information in the following table lists the administrative setup procedures that are specific to Siebel Clinical and procedures that might differ from the procedures of other Siebel Business Applications.

When setting up Siebel Clinical, use the information in this table in combination with the main resource, *Siebel Applications Administration Guide* .

Administrative Task	Description	For More Information
Managing accounts contacts in Siebel Life Sciences	• Activating workflows for accounts contacts • Enabling server components for accounts contacts • Generating column maps for accounts contacts list • Creating product data to appear in accounts contacts list	*Siebel Life Sciences Guide*
Creating a clinical program	• Creating protocols • Revising protocols • (Optional) Setting up regions • Defining a subject visit template	*Setting Up Clinical Trials* *Administering Clinical Subjects and Clinical Visits* *Managing Sites and Contacts for Clinical Trials*
Managing sites	• Creating protocol site templates • Creating assessment templates for contacts and accounts • Maintaining contact and account information • Setting up contracts for sites	*Managing Sites and Contacts for Clinical Trials*
Setting up clinical payments	• Setting up standard payment amounts in subject visit templates • Adjusting payment amounts and generating payments for sites	*Setting Up and Making Clinical Payments*
Creating trip report templates	• Creating trip report templates • Approving trip report templates	*Administering and Using Clinical Trip Reports*
Creating activity templates for projects	• Creating activity templates for projects	*Managing Clinical Projects*
Importing data	• Importing data with Siebel Enterprise Integration Manager	*Siebel Life Sciences Guide*

Administrative Task	Description	For More Information
	• Importing, extracting, and routing syndicated data • Charting denormalized syndicated data	
Configuring Siebel Clinical	• Configuring user properties for business components • Configuring user properties for business services • Configuring applet properties • Configuring field properties • Configuring workflows • Customizing Web services	*Developer's Reference for Siebel Clinical*

About the My Team's Filter

The visibility filter appears on many screens. It provides a list of filters, such as My Contacts, My Team's Contacts, and All Contacts. These filters determine the records that appear in the view.

The behavior of the My Team's filter varies from screen to screen. In some screens, this filter displays those records where the *primary* member of the team reports to the user. In other screens, this filter displays records where *any* of the team members report to the user.

The Manager List Mode user property in the business component determines this behavior. If the Manager List Mode user property is active and set to Team, then the My Team's filter displays all records where the user's subordinate is on the team but is not necessarily the primary member.

The following information lists the default setting of the Manager List Mode user property for some Siebel Clinical screens and business components.

Screen	Business Component	Manager List Mode
Accounts	Accounts	Inactive
Contacts	Contact	Inactive
Protocols	Clinical Protocol	Active
Site Management	Clinical Protocol Site	Active

Using Siebel Assignment Manager in Siebel Clinical

Siebel Assignment Manager allows the Siebel administrator to automatically assign tasks to specific people. For this assignment, however, the Siebel administrator must first define assignment rules for each task. For more information about using and implementing Siebel Assignment Manager, see *Siebel Assignment Manager Administration Guide* . For additional information about creating territories and running territory realignments, see *Siebel Territory Management Guide* .

This topic provides Siebel Assignment Manager information that is specific to Siebel Clinical.

Predefined Assignment Objects

Some of the predefined assignment objects and underlying criteria described in *Siebel Assignment Manager Administration Guide* are modified in Siebel Life Sciences to support pharmaceutical business processes. The following table describes the assignment objects that are changed in Siebel Life Sciences.

Note: Assignment Item Type Industry Name is not supported. This assignment rule is defined for Siebel Business Applications and currently conflicts with Siebel Life Sciences assignment rules. Siebel Life Sciences uses the assignment item type SIC (Standard Industrial Classification) Code.

Assignment Object	Modifications
Account	The assignment criteria SIC Code is renamed Account Class of Trade. Its assignment criteria include: • Account City State Country • Account Brick The source table for Account Brick is changed to S_CON_ADDR, and the source column for Account Brick is changed to BRICK_ID.
Contact	This assignment object is created specifically for Siebel Life Sciences and is not described in *Siebel Assignment Manager Administration Guide* . Its assignment criteria include: • Contact • Contact Medical Specialty Code • Contact Wildcard • Contact City • Contact State • Contact Country • Contact Zip Code • Contact City State Country • Contact Brick

Assignment Object	Modifications
	• Medical Specialty • Organization • Position

Contact Assignments in Siebel Clinical

In most Siebel Business Applications, contact assignment is based on the primary address. This process is different for Siebel Life Sciences. A contact in Siebel Life Sciences can have multiple addresses, and each representative on the contact's sales team can indicate a different primary address for the same contact. For this reason, do not base the contact assignment on the primary address.

For example, Representative A might indicate a hospital address as the primary address, while Representative B might indicate a private-office address as the primary address. In the All Contacts and My Team's Contacts views, the primary address that appears is the address that the primary team member assigns. For more information, see *Predefined Assignment Objects*.

Contact Denormalization Mode in Siebel Life Sciences

Contact Denormalization mode in Siebel Life Sciences differs from the description of the mode in *Siebel Assignment Manager Administration Guide* in the following ways:

- This mode denormalizes positions from the account team table to the contact team table for all contacts *directly* affiliated with an account. Users can specify a direct affiliation between a contact and an account by selecting:
  - The Direct field in the Account Affiliations view of the Contacts screen.
  - The Direct field in the Contact Affiliations view of the Accounts screen.

  For more information, see *Siebel Life Sciences Guide* .
- This mode does *not* denormalize positions from the opportunity team table to the contact team table.
- You must run this mode after separately running batch mode jobs for contacts and accounts. Run the batch mode jobs in the following order:
  a. Contacts
  b. Accounts
  c. Contact Denormalization

Contact Denormalization in Siebel Life Sciences has the following additional important rules, requirements, and exceptions:

- **Running Contact Denormalization mode in Dynamic mode.** To activate the Contact Denormalization Policy, set the expiration date to a future date or leave it blank. Then generate the database triggers by running Generate Triggers.
- **Running Contact Denormalization mode in Batch mode.** Remember to specify the following parameters:

```
Object Name=Contact Denormalization

Assignment Mode=Denorm
```

- **Contact Denormalization mode does not evaluate rules.** Therefore, you do not have to create a rule-based object for Contact Denormalization to run Assignment Manager in this mode. Also, because it does not evaluate rules, Contact Denormalization mode does not set the primary team position.
- **Contact Denormalization assigns contacts to employees who are on the account team to which the contacts are directly affiliated.** To reduce the number of contact-to-position relationship (S_POSTN_CON) rows routed to the manager's local database, the value of the `ASGN_DNRM_FLG` field is set to `"N"`. With this default setting, the contacts that the Contact Denormalization process assigns to team members are not visible to managers on their local databases. However, if you want managers to see all contacts that are assigned to their team members, regardless of the assignment method, then set `ASGN_DNRM_ "Y"`.

Setting Up Mobile Web Clients for Position Rollup

In Siebel Clinical, a CRA (clinical research associate) can create sites and assign employees to positions at the site level. When the CRA clicks the Position Rollup button, these positions become visible at the region and protocol levels. Typically, the CRA works in a disconnected mode, on a laptop computer.

The administrator must set up each mobile Web client to allow position rollups. The setup requires the following steps in Siebel Clinical:

- The administrator exports workflow processes and data maps from the server database to XML files.
- The administrator connects to a local client, imports the XML files to the client database and activates the workflow processes on the local client.

> **Note:** Users of the local client must have Workflow Process Definition, EAI DATA Map View, and EAI Data Map Editor in their user responsibilities to accept imported workflow processes and data maps.

Exporting Workflow Processes to the Local Client

Complete the procedure in this topic to export the workflow processes to the local client.

To export the workflow processes to the local client

1. Export the Clinical Assign Position From Region and Clinical Assign Position From Site workflows to XML files.
2. Import the two XML files to the local client, and activate the workflows.

   For information about exporting and importing workflow processes, see *Siebel Business Process Framework: Workflow Guide* .

Exporting DTE Data Maps From the Server Database to an XML File

Complete the procedure in this topic to export DTE data maps from the server database to an XML file.

To export DTE data maps from the server database to an XML file

1. In Siebel Clinical, connect to the server database.

2. Navigate to the Administration - Integration screen, then the Data Maps view.
3. In the Integration Object Map list, query for Clinical*.

   The query returns the following records: Clinical Region Position to Protocol Position Map, Clinical Site Position to Account Position Map, Clinical Site Position to Protocol Position Map, and Clinical Site Position to Region Position Map.
4. Click Menu (the cogwheel icon), and select Export Data Map.
5. In the dialog box, check Export All Rows in Current Query and click Export.
6. In the dialog box, select Save to Disk, select a location, and save the data maps as PositionRollupDataMap.xml.

Importing DTE Data Maps to a Local Client From an XML File

Complete the procedure in this topic to import DTE data maps to a local client from an XML file.

To import DTE data maps to a local client from an XML file

1. In Siebel Clinical, connect to the local client.
2. Navigate to the Administration - Integration screen, then the Data Maps view.
3. In the Integration Object Map list, click Menu (the cogwheel icon), and select Import Data Map.
4. In the dialog box, select Browse and find PositionRollupDataMap.xml.

   For information about creating this file, see *Exporting DTE Data Maps From the Server Database to an XML File*.
5. In the Integration Object Map list, query for Clinical*Position*.

4 Setting Up Clinical Trials

Setting Up Clinical Trials

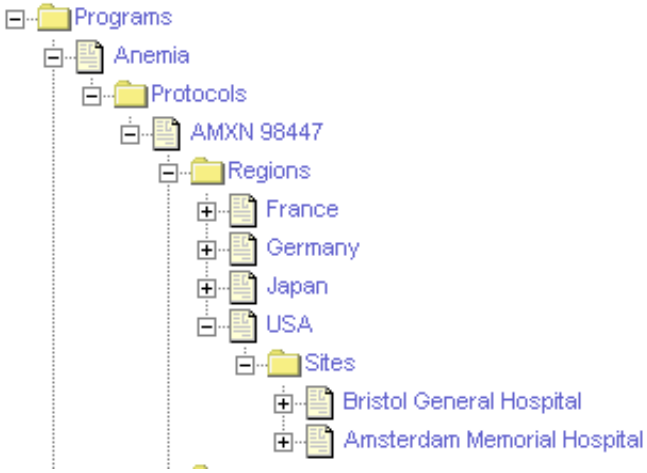
This chapter describes how to set up a clinical program, protocol, region, and site in Siebel Clinical. It includes the following topics:

About Setting Up Clinical Trials

This chapter describes the main steps to carry out a clinical trial using Siebel Clinical. Following the procedures in this chapter you can:

- Create a clinical program and clinical protocols.
- Set up document tracking at the protocol, region, and site levels, and for accounts and contacts.
- Set up and revise subject visit templates for a protocol.
- Enter data on accounts, sites, and contacts.
- Screen and enroll subjects.
- View charts showing subject status and subject enrollment rates.
- Review payments to the protocol.

The following image illustrates the important hierarchical relationship of programs, protocols, regions, and sites. In this example, the Bristol General Hospital (site) in the USA region is participating in the AMXN 98447 protocol, which is part of the Anemia program.



Scenario for Clinical Trials

This topic gives one example of how clinical trials might be used. You might use clinical trials differently, depending on your business model.

The clinical director and the study manager, working for a CRO (clinical research organization), or pharmaceutical, biotech, or medical device company, have administrator responsibilities in Siebel Clinical to:

- Set up a new program for the treatment study.
- Create one or more protocols designed to assess the safety and efficacy of certain compounds in the treatment of the disease.
- Set up the geographic regions where you carry out the protocols.
- Compile a list of documents that are critical to the study and implement tracking at the protocol, region, and site levels, and for accounts and contacts.
- Create a subject visit template to facilitate consistent application of the protocol across sites and subjects. End users can use this template to set up subject visit schedules and activities according to the guidelines laid out in the protocol.

  After the program, protocol, and subject visit templates are set up, the CRAs (clinical research associates) who are the end users of the Siebel Clinical product do the following:

  - Enter data about the:
    - Sites where you carry out the protocols.
    - Members to assign to the teams at the site, region, and protocol levels.
    - Accounts or institutions, such as hospitals and clinics where the studies are conducted.
    - Contacts or site personnel, such as investigators, site coordinators, and nurse practitioners who carry out the protocols.
    - Recruited subjects for the clinical trial.
  - Screen and enroll subjects and, if necessary, rescreen the subjects.

- Use the subject visit template to set up detailed schedules for the subject visits to the sites.
- Track required documents at the protocol, region, or site level, or for accounts or contacts.

> **Note:** Site personnel can use Siebel Site Portal to enter subject data and set up screening and enrollment schedules for subject visits. For more information about Siebel Site Portal, see *Siebel Life Sciences Portals Guide* .

After subjects are enrolled in the trial, the clinical director, study manager, or CRAs can use the charting features of Siebel Clinical to review the progress of the trial. Two informative metrics are the subject status and subject enrollment rate. These metrics are plotted for an individual site, for a region, and for a protocol.

Process of Managing Clinical Trials

This topic details sample tasks that administrators and end users often perform when managing clinical trials. Your company might follow a different process according to its business requirements.

Perform the tasks in this topic in the order presented. For example, a protocol must exist before you can create its subject visit template.

Administrator Procedures

The following list shows the tasks administrators typically perform to manage a clinical trial:

1. *Creating Clinical Programs*
2. *Setting Up Clinical Protocols*
3. *Tracking and Revising Team Assignment History*
4. *Creating and Revising Versions for Clinical Protocols*
5. *Associating Clinical Protocols with Accounts*
6. (Optional) *Setting Up Clinical Regions*
7. *Associating Clinical Regions with Accounts*

End-User Procedures

The following list shows the tasks CRAs (clinical research associates) typically perform at the site level to manage a clinical trial:

1. (Optional) *Creating Accounts and Contacts for Clinical Trials*
2. *Creating Sites for Clinical Trials*
3. (Optional) *Creating Satellite Sites for Clinical Trials*
4. *Associating Sites with Accounts*
5. *Risk Assessments for Clinical Trials*

Creating Clinical Programs

The clinical program is the highest-level initiative in Siebel Clinical. You associate protocols, regions, sites, and subjects with a program.

You can associate multiple regulatory applications with a program. You create these application records. Before you can create an application record, you must define the product that is associated with the application. For more information about defining products, see *Siebel Life Sciences Guide* .

This task is a step in *Process of Managing Clinical Trials*.

To create a clinical program

1. Navigate to the Administration - Clinical screen, then the Program List view.
2. In the Program list, create a new record and complete the necessary fields. Some fields are shown in the following table.

Field	Comments
Program	Type the name of the clinical program.
Mechanism	Select the partners associated with the clinical program.
Application	Select a record containing details of the application for the clinical program. If necessary, create an application record. This record contains values for the following fields: **Number.** The number assigned to the application when it is submitted to the regulatory agency, for example the (A)NDA or IND number. **Type.** The type of application, such as CTN, IND, or CTX. **Sub-Type.** The application filer, for example, a company or an investigator. **Filed.** Whether the application is filed with the specified regulatory agency. **Product.** The applicable product for the application. You must complete this field before you can create a protocol for the program. **Indication.** The clinical indication for the application.

3. (Optional) Drill down on the Program field of the new record and associate files with the clinical program.

Setting Up Clinical Protocols

You can associate multiple protocols with a program. When you create a protocol record, you can also add extra information about the protocol, such as financial information, central laboratory information, and so on.

This task is a step in *Process of Managing Clinical Trials*.

To set up a clinical protocol

1. Navigate to the Administration - Clinical screen, then the Protocol List view.
2. In the Protocol list, create a new record and complete the necessary fields. Some fields are shown in the following table.

Field	Comments
Protocol #	Type an identifying number for the protocol.
Title	Type a descriptive title for the protocol.
Status	Select the status of the protocol, such as Planned, In Progress, or Completed.
Program	Select the name of the program for the clinical trial.
Product	Select the product for the clinical trial. You can select only the products that are associated with the clinical program, through the Application field in the Program List view, in the Clinical Product and Indication dialog box. For more information about creating a clinical program, see *Creating Clinical Programs*.
Phase	Select the phase of clinical trial, such as Phase I, II, or III.
Objective	Type the objective for the clinical trial.
Sponsor	Select the clinical trial sponsor.
Design	Select the type of study.
Regions Required	Select this field to indicate the sites for this protocol must belong to a region. For information about regions, see *Setting Up Clinical Regions*. When you select this field, you cannot create sites directly under protocols. You must create regions first, and then create sites that are associated with regions.

Field	Comments
Type	Select the purpose of the protocol.
Team	Select the team members who need access to the protocol, such as the study manager and others who monitor the clinical trial. For more information, see Step 3.
Approval Date	Select the date that the regulatory authority approves the protocol.
Currency Code	Select the currency that is used to display the payments, costs, and budgets for the protocol. The default value is USD (United States dollars). **Note:** You must specify the currency code for the protocol.
Planned Start Date	Select the planned start date for the study.
Exchange Date	Select the date that determines the exchange rate of the currency. By default, the exchange date for the protocol is the date that you create the protocol.
Planned End Date	Select the planned end date for the study.
Withholding Amount	Type the amount to withhold from each of the payments to the investigators until the trial is complete. You can overwrite this value at the region and site levels.
Actual Start Date	Select the date that the study begins.
# Planned Sites	Type the number of planned sites for the protocol.
# Planned Subjects	Type the number of planned subjects for the protocol.
Withholding %	Type the percentage to withhold from each of the payments to the investigators until the trial is complete. You can overwrite this value at the region and site levels.
Actual End Date	Select the date that the study concludes.

3. To add team members to the protocol, click the select button in the Team field to open the Team dialog box, and complete the following steps:

    a. Move the record for an available team member to the list of selected team members.

b. Click Position Rolldown.

   Multi-selected team members are added to the protocol as well as to all regions and sites belonging to the protocol.

c. Click OK.

   Each time a member is added to the team of a protocol, a tracking record is created in the Team History view with a proper start date for this tracking record. For more information, see *Automatically Assigning Team Members to a Protocol Using the Position Rolldown Button*.

   If you remove a member from the team of a protocol, then the end date of this record is automatically populated. For more information, see *About Removing Team Members From the Team of a Protocol*.

4. Drill down on the protocol number field, and navigate to the More Info view to add more information. Some fields are shown in the following table.

Field	Comments
Central Lab	Select the name of the laboratory associated with the study. You create this name in the Accounts screen.
CRO	Select the name of the clinical research organization that sponsors the trial. You create this name in the Accounts screen.

5. Navigate to the Team History view to view the details of the team member that is automatically added to the protocol in a previous step.

   From the Team History view you can administer and track team members who work on the protocol. This view also provides details about the role as well as the start and end dates. To administer and track the history of team members who work on a protocol and to determine their role, see *Tracking and Revising Team Assignment History*.

Tracking and Revising Team Assignment History

A typical clinical trial can span many months to years and often requires changes of study members. Rules and regulations require clinical organizations to keep records of study team assignments and to promote tight access controls so that only people who are assigned roles and responsibilities for a trial have the proper access to trial data.

When a person is no longer part of the clinical trial team, all access rights to the trial data cease. When necessary, the study manager can also manually create a tracking record independent of the team assignment. Similar functionality applies to region team and site team assignment. The Team History view allows you to administer and track team members who work on the protocol, region, or site. This view also provides details about the role as well as the start and end dates.

This task is a step in *Process of Managing Clinical Trials*.

To revise team assignment history

1. Navigate to the Administration - Clinical screen, then the Protocol List view.

2. In the Protocol list, drill down on the protocol number field of the protocol for which you want to create a new team assignment history.
3. Navigate to the Team History view.
4. In the History list, create a new record and complete the necessary fields. Some fields are shown in the following table.

Field	Comments
Role	Select the value that best describes the member's role.
Start Date	Select the start date and time for the team member. If you add a member from the team of a protocol (either manually or by using the Position Rollup mechanism), then the start date is populated with the system date, and the end date is blank.
End Date	Select the end date and time for the team member. If you remove a member from the team of a protocol (either manually or through reverse of Position Rollup mechanism), then the end date is populated with the system date. The system date overrides the date that exists in the End Date field if the record is not read-only.
Lock Record	Select this field to make the record read-only and to make the End Date field a required field.

Automatically Assigning Team Members to a Protocol Using the Position Rolldown Button

When you add a team member to a protocol, click the Position Rolldown button to add the member to all regions and all sites under the protocol. You can add a member to the team only once.

When you click the Position Rolldown button to add a member to the team of a protocol, a record is created, where applicable, in each of the Team History views for all regions and all sites belonging to the protocol. The Position Rolldown mechanism automates the addition of team members to the Team History view for sites and the Team History view for regions as if they are manually added.

About Removing Team Members From the Team of a Protocol

When you remove a team member from the protocol, the team member is removed from either the protocol, or from all protocols, regions and sites belonging to the protocol.

When you remove a member from the team of a protocol (either manually or through Position Rollup or Position Rolldown), the End Date field of the team member's record, if present, is updated with the system date. However, if the record is read-only, then the initial value in the End Date field is not updated. The Position Rolldown mechanism automates the update of the End Date field of the assignment records as if they are manually removed from the team of the sites and regions.

Note: A prompt appears asking whether to remove the member from only the protocol or from all protocols, regions, and sites belonging to the protocol.

Creating and Revising Versions for Clinical Protocols

You can track and manage protocol versions using Siebel Clinical. The study manager can create a tracking record for the original protocol and for each subsequent version.

This task is a step in *Process of Managing Clinical Trials*.

To create a version for a clinical protocol

1. Navigate to the Administration - Clinical screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol for which you want to create a new protocol version.
3. Navigate to the Protocol Versions view.
4. In the Protocol Versions list, create a new record and complete the necessary fields. Some fields are shown in the following table.

Field	Comments
Original Version	Select this field if this version is the first version of the protocol. If this field is checked, then the Amendment Version field is read-only.
Amendment Version	Select the version number of the protocol version, for example, Version 1, Version 2, and so on.
Date	Select the date and time that you approve the new version.

Associating Clinical Protocols with Accounts

An account is the institution from which you manage clinical trials. Typically, it is the facility where the investigators conduct the trials. You can track as accounts IRBs (institutional review boards), central laboratories, CROs (clinical research organizations), and other subcontractors. You can associate a clinical protocol with multiple accounts.

This task is a step in *Process of Managing Clinical Trials*.

To associate a clinical protocol with an account

1. Navigate to the Administration - Clinical screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol that you want to associate with an account.
3. Navigate to the Accounts view.
4. In the Accounts list, create a new record and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Account	Select the name of the account.
Type	Select the type of account, such as IRB, CRO, or vendor. System administrators can configure the values that appear in the Type pick list.
Central IRB	Select this field to indicate that all sites use a central institutional review board.
Regional CRO	Select this field to indicate that a clinical research organization provides services to all sites in the clinical region.

Setting Up Clinical Regions

Clinical trials often occur in multiple countries. The region level in Siebel Clinical allows you to track and view study data by country and region.

Regions are optional for protocols. However, if you choose to use regions by selecting the Regions Required field in the protocol record, then each site associated with the protocol must belong to a region. One of the advantages of using regions is that regions provide another way of grouping sites and subjects. For example, you can chart subject enrollment by region in addition to by protocol and by site.

Note: You cannot create regions for a protocol unless the Regions Required field is selected for the protocol. For more information, see the description of the Regions Required field in *Setting Up Clinical Protocols*.

This task is a step in *Process of Managing Clinical Trials*.

To set up clinical regions

1. Navigate to the Administration - Clinical screen, then the Region List view.
2. In the Region list, create a new record and complete the necessary fields. Some fields are shown in the following table.

   Create a region record for each country or geographical area where sites are or will be participating in the protocol.

Field	Comments
Protocol #	Select the protocol for the region. Only protocols that require regions are listed in the Pick Protocol dialog box.

Field	Comments
Region	Select the geographic region to which the site belongs.
Protocol Region	Displays the name of the region. This field is automatically populated with the protocol number and the region name.
# Planned Sites	Type the number of planned sites for the region.
# Planned Subjects	Type the number of planned subjects for the region.
Team	Select the team members associated with the protocol to which the region belongs. For more information, see Step 3.
No Site Info	Select this field to indicate that no site information is available under a region. Only summary information about site enrollment is available for such a region.
Currency Code	Select the currency that is used to display the payments, costs, and budgets in the region. The default value is USD (United States dollars). **Note:** You must specify the currency code for each region if multiple currencies are used for the trial.
Withholding Amount	Type the amount to withhold from each of the payments to the investigators until the trial is complete. The default value is the Withholding Amount field for the protocol. However, you can overwrite the Withholding Amount field for the protocol in this field at the region level.
Withholding %	Type the percentage to withhold from each of the payments to the investigators until the trial is complete. The default value is the Withholding % field for the protocol. However, you can overwrite the Withholding % field for the protocol in this field at the region level.
Exchange Date	Select the date that determines the exchange rate of the currency. By default, the exchange date for the region is the date that you create the region. You can change this date in response to changes in currency rates. However, changes to the exchange date at the region level take effect only when the exchange date also changes at the system level. For more information, see *Siebel Applications Administration Guide* .

3. To add team members to the region, click the select button in the Team field to open the Team dialog box, and complete the following steps:
    a. Move the record for an available team member to the list of selected team members.
    b. Click Position Rolldown.

       Multi-selected team members are added to all the site teams of this region.

       Note: The Position Rolldown button for region applies only to the sites after a region.

    c. Click Position Rollup.

       Multi-selected team members are added to the protocol to which the region belongs. To administer and track the history of team members who work on a protocol in a region and to determine their role, see *Tracking and Revising Team Assignment History*.
    d. Click OK.
4. (Optional) Drill down on the Region field, and navigate to the More Info view to add more information.

Automatically Assigning Team Members Using the Position Rollup and Rolldown Buttons

When you click the Position Rolldown and Position Rollup button, a record is created, where applicable, in each of the Team History views for the protocol and all sites belonging to the region. The Position Rolldown mechanism automates the addition of team members to the Team History view for sites and the Team History view for protocols as if they are manually added. To remove a team member from the protocol, see *About Removing Team Members From the Team of a Protocol*.

Creating Assignment Team History for Regions

The Team History view allows you to administer and track team members who work in the region. It also provides details about the roles as well as the start and end dates.

To create assignment team history for a region

1. Navigate to the Administration - Clinical screen, then the Region List view.
2. In the Region list, drill down on the Region field of the region for which you want to create a new team assignment history.
3. Navigate to the Team History view.
4. In the History list, create a new record and complete the necessary fields.

Associating Clinical Regions with Accounts

An account is the institution from which you manage clinical trials. Typically, it is the facility where investigators conduct the trails. You can track as accounts IRBs (institutional review boards), central laboratories, CROs (clinical research organizations), and other subcontractors. You can associate a clinical region with multiple accounts.

This task is a step in *Process of Managing Clinical Trials*.

To associate a clinical region with an account

1. Navigate to the Administration - Clinical screen, then the Region List view.
2. In the Region list, drill down on the Region field of the region that you want to associate with an account.
3. Navigate to the Accounts view.
4. In the Accounts list, create a new record and complete the fields as necessary. Some fields are shown in the following table.

Field	Comments
Account	Select the name of the account.
Type	Select the type of account, such as IRB, CRO, or vendor. System administrators can configure the values that appear in the Type picklist.
Central IRB	Select this field to indicate that all sites use a central institutional review board.
Regional CRO	Select this field to indicate that a clinical research organization provides services to all sites in the clinical region.

Creating Accounts and Contacts for Clinical Trials

An account is the institution from which you manage clinical trials. Typically, it is the facility where the investigators conduct the trials. You can track as accounts IRBs (institutional review boards), central laboratories, CROs (clinical research organizations), and other subcontractors. You can associate multiple sites with an account, and an account can carry out multiple protocols.

A contact is a person working at a clinical site. Contacts include investigators, typically medical professionals who are also researchers, and site coordinators, who might be the practicing nurses administering the treatment plan according to the clinical protocol.

The Siebel administrator generally bulk loads data on accounts and contacts, but end users can create and modify these records as needed. For information about importing data into your Siebel Life Sciences database, see *Siebel Life Sciences Guide* .

This task is a step in *Process of Managing Clinical Trials*.

Creating Accounts

Complete the procedure in this topic to create an account.

To create an account

1. Navigate to the Accounts screen, then the Accounts List view.

2. In the Accounts list, create a new record and complete the necessary fields. Some fields are shown in the following table. To access more fields, click the show more button in the account form.

Field	Comments
Site	Type a description of the location or function of the account, such as headquarters, corporate, or San Francisco.
Account Type	Select the type of account, such as Hospital, Clinic, IRB, and so on.
Account Team	Select the members assigned to the account team. The team member who creates the account record is the primary team member.
Address	Select the addresses for the account by picking from existing addresses or by entering new addresses. Avoid duplicating addresses by checking if an address exists before entering a new one.

3. Drill down on the Name field of the account, and navigate to the More Info view to add more information. Some fields are shown in the following table.

Field	Comments
Synonyms	Select the synonyms for the account. This field allows you to refer to accounts in the way that you prefer. For example, an account named A/B Products, Inc., might have the following synonyms: AB, A/B, and AB Products. When you search for an account or enter an account in another part of your Siebel Business Application, you can use a synonym instead of the actual name.
Territories	Select the territories that are associated with the account.

4. Navigate to views, such as the Activities view, the Addresses view, and so on to add more information to the account record.

   For more information about creating and maintaining account affiliations, see *Siebel Life Sciences Guide* .

Creating Contact Records

Complete the procedure in this topic to create a contact record.

To create a contact record

1. Navigate to the Contacts screen, then the Contacts List view.

2. In the Contacts list, create a new record and complete the necessary fields. Some fields are shown in the following table.

Field	Comments
My Address	Select the addresses for the contact. A contact can have more than one address. You must specify one address as the primary address. Each CRA (clinical research associate) assigned to the contact can specify a different address as the primary address. For example, one CRA might specify a private office as the primary address, while another CRA might specify a hospital department as the primary address.
Team	Select the CRAs assigned to the contact. The team member who creates the contact record is the primary team member.

3. Navigate to other views to add or associate additional information with the contact record.

   For example, use the Relationships view to associate site coordinators and other site personnel with the contact. For more information about creating and maintaining contact records, see *Siebel Life Sciences Guide* .

Creating Sites for Clinical Trials

The *site* is an account that a principal investigator manages for a particular protocol. In Siebel Clinical, a separate site record must exist for each unique combination of a protocol, account, and principal investigator. Before starting to create sites for clinical trials, review *Process of Managing Sites and Contacts for Clinical Trials* for more information.

This task is a step in *Process of Managing Clinical Trials*.

To create a site for clinical trials

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, create a new record and complete the necessary fields. Some fields are shown in the following table.

Field	Comments
Satellite Site	Read-Only field. A star in this field indicates that this is a satellite site.
Site #	Type the number to assign to the site. This field is not required when the Status field for the site is Planned or Not Initiated. This field becomes required after a site is initiated.
Protocol #	Select the protocol from the list of existing protocols in the Pick Protocol dialog box.
Region	Select the region name if regions are required for the protocol.

Field	Comments
Parent Site	Read-Only field. Populated only for satellite sites, this field indicates the name of the parent site to which the satellite site belongs.
Status	Select the status of the site, for example, Planned, Initiated, Enrolling, and Closed. A preconfigured state model allows for a structured state transition.
PI Last Name	Select the last name of the principal investigator for the site. To change the principle investigator for the site, you select a different contact in this field. For more information about adding other contacts to the site, see *Associating Sites with Contacts*. When you click the select button in this field, the Pick Contacts dialog box appears. After you select an account for the site, click the Affiliated Contacts button in this dialog box to view only those contacts who are affiliated with the account for the site.
Account	Select the primary account (the institution where the protocol is managed) for the site. To change the primary account for the site, you select a different account in this field. For more information about adding other accounts to the site, see *Associating Sites with Accounts*.
Team	Select the team members for the site. The Primary field is populated for the site record creator, and only the team manager can change this field through the My Team's Sites view. Resource management is a manager's responsibility. For more information, see Step 3.
No Subject Info	Select this field to indicate that no subject information is available for a site. Only summary information about subject enrollment is available for such a site.
Last Completed Visit Date	Select this field to use the date of the last completed visit for rescheduling subject visits. Deselect this field to prompt the user to enter a new start date for rescheduled visits. All uncompleted subject visits are rescheduled using the new date.
Versions	Select the version of the subject visit template for the site. For more information, see Step 4.
Currency Code	Select the currency that is used to display the payments, costs, and budgets for the site.
Withholding Amount	Type the amount of the total payment to withhold from the investigators until the trial is complete. You can set the default value at the region or protocol level, but you can overwrite the value at the site level.

Field	Comments
Withholding %	Type the percentage of the total payment to withhold from the investigators until the trial is complete. You can set the default value at the region or protocol level, but you can overwrite the value at the site level.
Exchange Date	Select the date that determines the exchange rate of the currency. By default, the exchange date for the site is the date that you create the site. You can change this date in response to changes in currency rates. However, changes to the exchange date at the site level take effect only when the exchange date also changes at the system level. For more information, see *Siebel Applications Administration Guide* .

3. To add team members to the site, click the select button in the Team field to open the Team dialog box, and complete the following steps:
   a. Move the record for an available team member to the list of selected team members.
   b. Click Position Rollup.

      If the Regions Required field is selected for the protocol record, then multi-selected team members are added to the region and protocol to which the site belongs.
   c. Click OK.
4. Click the select button in the Versions field and complete the following steps:
   a. Select the version of the subject visit template to use at the site.

      Only the template versions related to your protocol are available for selection.
   b. Enter a date in IRB Approval Date field for the selected version.

      You cannot activate the template version without the IRB (institutional review board) approval date.
   c. Select the Active field to make the selected version the active version at the site.

      Only one version can be active at a time. The active template is used when activities are generated for a subject. For more information about protocol versions, see *Tracking and Revising Team Assignment History*.
   d. Click OK
5. (Optional) Drill down on the site number field, and navigate to the More Info view to add more information. Some fields are shown in the following table.

Field	Comments
Address	Select one of the principal investigator's addresses as the site address.
# Screen Failure	Displays the number of subjects that fail the screening.

Field	Comments
Last Subject Off Study	Displays the date that the last subject completes the study. (This field is automatically rolled-up from the subject data.)
First Subject Enrolled	Displays the date that you enroll the first subject in the study. (This field is automatically rolled-up from the subject data.)
# Early Terminated	Displays the number of subjects who terminate the study before it is complete.
Contract Amount	Displays the sum of all contract amounts for the site. For more information, see *Associating Contracts with Sites*.
Paid To Date	Displays the amount of money that you paid to date to the investigators.
Earned To Date	The amount of money that investigators earned to date.
Activate for Synchronization	Select this field to activate the site for synchronization. This field is required for integration with Oracle Health Sciences InForm. When this field is checked, a new integration object for the protocol site is sent to Oracle Health Sciences InForm. The integration object creates the site in Oracle Health Sciences InForm, or updates the site, if it already exists. This field is read-only until the following conditions are met: o The Synchronize Active Study Sites field of the protocol is set to true. o The Primary Site Address field is populated.
Primary Site Address	Select the primary address for the site. This field sets the primary location of the site for the study in Siebel Clinical. The Addresses dialog box displays all addresses for the site. This field is required for integration with Oracle Health Sciences InForm, and populates the site address when the site is created in Oracle Health Sciences InForm.

Automatically Assigning Team Members to a Site Using the Position Rollup Button

When you add a member to a team for a site (either manually or through the Position Rollup mechanism), a record is created in the Team History view, with the Start Date field set to the system date by default, and with a blank End Date field. To remove a team member from the protocol, see *About Removing Team Members From the Team of a Protocol*.

Creating Assignment Team History for Sites

The Team History view allows you to administer and track team members who work on the site. It also provides details about the roles as well as the start and end dates.

To create assignment team history for a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to create a new team assignment history.
3. Navigate to the Team History view.
4. In the Team History list, create a new record and complete the necessary fields.

About Removing Team Members From the Team of a Site

When you remove a member from the team of a site (either manually or through Position Rollup), the End Date field of the team member's record, if present, is updated with the system date. However, if the record is read-only, then the initial value in the End Date field is not updated. The Position Rollup mechanism automates the update of the End Date field of the assignment record as if it is manually removed from the team.

> **Note:** A prompt appears asking whether to remove the member from only the site or from all sites, regions, and protocols belonging to the site including these particular sites and all other sites within this protocol that include this user as a team member.

Creating Satellite Sites for Clinical Trials

The *satellite site* is a study site that is linked to an existing parent site where the parent site and the satellite site share the same principal investigator. Subjects are seen by the same principal investigator and visit both the parent site and the satellite site according to their own business requirements. Before starting to create satellite sites for clinical trials, review *Managing Satellite Sites and Contacts for Clinical Trials* for more information.

This task is a step in *Process of Managing Clinical Trials*.

To create a satellite site for clinical trial

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site Visits list, select My Sites in the visibility filter.

   All site visits that you own appear.
3. In the Protocol Site list, drill down on the Site Number field of the site under which you want to create the satellite site.
4. Navigate to the Satellites Sites view.

   This view contains the following information:

   - **Subject Info.** Shows the subject enrollment data accrued for a parent site from all the satellite sites under it.
   - **Financials.** Shows the financial data accrued for a parent site from all the satellite sites under it.
   - **Satellite Sites.** Lists all the satellite sites for the parent site and provides the ability to create a new satellite site for the parent site.

5. In the Satellites Sites list, create a new record and complete the necessary fields. Some data is inherited from the parent site and cannot be changed. Some fields are shown in the following table.

Field	Comments
Satellite Site Number	Type the number to assign to the satellite site.
Account	Select the primary account (the institution where the protocol is managed) for the site. To change the primary account for the site, you select a different account in this field. For more information about adding other accounts to the site, see *Associating Sites with Accounts*.
PI Last Name	Read-only field. The last name of the principal investigator, inherited from the parent site, for the satellite site. This is a read-only field.
PI First Name	Read-only field. The first name of the principal investigator, inherited from the parent site, for the satellite site. This is a read-only field.
Status	The status of the satellite site, which is Planned by default. Other statuses are Initiated, Enrolling, and Closed.
Site Initiated	The date the satellite site was created. This field is blank by default.
Site Terminated	The date the satellite site was terminated. This field is blank by default.
Team	Read-only field. The team for the satellite site, inherited from the parent site. For more information, see *Creating Sites for Clinical Trials* (Step 3.).

6. Drill down on the Satellite Site Number field to complete more fields as necessary. Some data is inherited from the parent site and cannot be changed. Some fields are shown in the following table.

Field	Comments
Protocol #	Read-only field. The protocol, inherited from the parent site, for the satellite site.
Region	Read-only field.The region, inherited from the parent site, for satellite site.
Parent Site	Read-only field. The parent site for the satellite site.
Versions	Read-only field.The version of the subject visit template, which is inherited from the parent site. Only one version can be active at a time. The active template is used when

Field	Comments
	activities are generated for a subject. For more information about protocol versions, see *Tracking and Revising Team Assignment History*
Exchange Date	Select the date that determines the exchange rate of the currency. By default, the exchange date for the site is the date that you create the site. You can change this date in response to changes in currency rates. However, changes to the exchange date at the site level take effect only when the exchange date also changes at the system level. For more information, see *Siebel Applications Administration Guide* .
Withholding Amount	Type the amount of the total payment to withhold from the investigators until the trial is complete. You can set the default value at the region or protocol level, but you can overwrite the value at the site level.
Withholding %	Type the percentage of the total payment to withhold from the investigators until the trial is complete. You can set the default value at the region or protocol level, but you can overwrite the value at the site level.
Currency Code	Read-only field. The currency, inherited from the parent site, that is used to display the payments, costs, and budgets for the satellite site.
Last Completed Visit Date	Select this field to use the date of the last completed visit for rescheduling subject visits. Deselect this field to prompt the user to enter a new start date for rescheduled visits. All uncompleted subject visits are rescheduled using the new date.

7. (Optional) Navigate to the More Info view to add more information. Some fields are shown in the following table.

Field	Comments
Address	Select one of the principal investigator's addresses as the site address.
# Screen Failure	Displays the number of subjects that fail the screening.
Last Subject Off Study	Displays the date that the last subject completes the study. (This field is automatically rolled-up from the subject data.)
First Subject Enrolled	Displays the date that you enroll the first subject in the study. (This field is automatically rolled-up from the subject data.)

Field	Comments
# Early Terminated	Displays the number of subjects who terminate the study before it is complete.
Contract Amount	Displays the sum of all contract amounts for the site. For more information, see *Associating Contracts with Sites*.
Paid To Date	Displays the amount of money that you paid to date to the investigators.
Earned To Date	The amount of money that investigators earned to date.
Activate for Synchronization	Select this field to activate the site for synchronization. This field is required for integration with Oracle Health Sciences InForm. When this field is checked, a new integration object for the protocol site is sent to Oracle Health Sciences InForm. The integration object creates the site in Oracle Health Sciences InForm, or updates the site, if it already exists. This field is read-only until the following conditions are met: o The Synchronize Active Study Sites field of the protocol is set to true. o The Primary Site Address field is populated.
Primary Site Address	Select the primary address for the site. This field sets the primary location of the site for the study in Siebel Clinical. The Addresses dialog box displays all addresses for the site. This field is required for integration with Oracle Health Sciences InForm, and populates the site address when the site is created in Oracle Health Sciences InForm.
Satellite Site Count	Displays the number of satellite sites associated with this site.

8. Assign subject visits to the satellite site as follows:

   a. Navigate to the Subjects view.
   b. Create a new Subject record and complete the necessary fields.
   c. Drill down on the Screening # field.
   d. Create a new Visit Plan record and complete the necessary fields. Some fields are shown in the following table. For more information about subjects visits, see *Defining Subject Visits*.

Field	Comments
Site	Select the site for the subject visit. The Sites pick list includes the parent site and all satellite sites under the parent site.

Field	Comments
Assigned To	Select the user ID of the person assigned to the subject visit.
Sequence	Type the sequence number of the visit.
Type	Read-only field. The type of visit, which is Unscheduled Visit by default.
Name	The name of the visit.

e. Add Activities to the subject visit as required and complete the necessary fields. For more information about activities, see *Defining Activities for Subject Visits* and *Associating Activities with Sites*.

9. Transfer (uncompleted) subject visits to or from the satellite site as required:

   a. Navigate to the Subjects view.
   b. Drill down on the Screening # field.

      The Visits view of the Subjects screen appears showing the Visit Plans.
   c. In the Site field, select the site to which you want to transfer the (uncompleted) subject visits to.

      The Sites pick list includes the parent site and all the satellite sites under the parent site. You can transfer subject visits from one satellite site to another satellite site or to the parent site as required. For more information about transferring subjects, see *Transferring Clinical Subjects*.
   d. Navigate to the Transfer History view and review all subject transfers against the subject.

      The Transfer History view includes the following information for each subject transfer: Source Site Name, Destination Site Name, Transfer Date, Transferred By, Status at Transfer, Description.

10. Navigate to the Site Management screen, then the Subject Transfer History view and review all subject transfers against the site.

    - The Subject In applet lists all subject visits transferred to the site.
    - The Subject Out applet lists all subject visits transferred from the site.

Associating Sites with Accounts

An account is the institution from which you mange clinical trials. Typically, it is the facility where the investigators conduct the trials. You can track as accounts IRBs (institutional review boards), central laboratories, CROs (clinical research organizations), and other subcontractors. In the Accounts view of a site, you can associate the site with multiple accounts.

A record for the account that you select in the Account field of the site record is automatically created in the Accounts view of the site. This record is automatically populated with a value of Site Primary in the Type field. You cannot delete this record or change its field values unless you select a new primary account in the Account field of the site record.

You can associate accounts for clinical protocols and for clinical regions with sites. For more information, see *Associating Accounts with Sites*.

This task is a step in *Process of Managing Clinical Trials*.

To associate a site with an account

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site that you want to associate with an account.
3. Navigate to the Accounts view.
4. In the Accounts list, create a new record and complete the necessary fields.

   Some fields are described in the following table.

Field	Comments
Type	Select the type of account. The Site Primary value for this field is automatically populated for the primary account of the site. In the Accounts view, you cannot change this value, or assign this value to another account. To change the primary account for the site, you change the value in the Account field of the form for the site record.
End Date	Select the date that the account is inactive to inactivate the account. You can select a past date, but not a future date. You might want to inactivate accounts instead of deleting them so that you can view the accounts that are no longer associated with the site. If you select a new primary account in the Account field of the form for the site record, then this field is automatically populated with the current date for the prior primary account, but you can change this date to a date in the past.

Risk Assessments for Clinical Trials

You can create risk assessment templates and perform risk assessments for clinical trials at the following levels:

- Clinical (for generic assessment of a program, protocol, region, or protocol site)
- Clinical Program
- Clinical Protocol
- Clinical Region
- Clinical Protocol Site

For more information, see *Creating Risk Assessment Templates* and *Performing Risk Assessments for Clinical Trials*.

Creating Risk Assessment Templates

A Risk Assessment and Categorization Tool (RACT) template for the Clinical level of risk assessment is available in the preconfigured Siebel Clinical application. Administrators select a level (or type) of risk assessment in the Type field when they create an assessment template. They can create additional assessment templates with associated attributes using the RACT Templates view of the Administration - Clinical screen.

To create a risk assessment template

1. Navigate to the Administration - Clinical screen, then the RACT Templates view.
2. In the RACT Templates list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Assessment	Type in the name of the template.
Type	Select a value that specifies the type of risk assessment template, which can be one of the following: o Clinical o Clinical Program o Clinical Protocol o Clinical Protocol Site o Clinical Region
Active	Select this check box to indicate that the risk assessment template is active, otherwise clear the check box.
Description	Type in a description of the risk assessment template.

3. In the Assessment Questions list, create a new record for each question you want to assess and complete the necessary fields as shown in the following table.

Field	Comments
Order	Enter the order number for the assessment question.
Category	(Mandatory field) Select a category for the assessment question, which can be one of the following: o Safety o Study Phase

Field	Comments
	○ Complexity ○ Subject Population ○ Technology ○ Data Collection, CRF source ○ Endpoints ○ Organization Experience ○ Investigational Product/Study Medication ○ IP Logistics/Supply Chain ○ Blinding ○ Operational Complexity ○ Geography
Questions	Type in the assessment question.
Weight	Type in the weight for the assessment question. The default value is 1.
Considerations	Type in any additional information relevant to the assessment question that should also be considered. Any information that you enter in this field automatically appears on screen (for example, as a tool tip) when the user places the mouse over the respective question during an assessment.

4. In the Question Values list, create records to further describe the assessment questions you created in the previous step, and complete the necessary fields as shown in the following table.

Field	Comments
Order	Enter the order number that corresponds to the assessment question.
Type	Select from the following values to describe the assessmenquestion: ○ Impact ○ Probability ○ Detectability
Value	Select the value that applies to the option that you select in the Type field. For Impact and Probability, the values available are: ○ High (3) ○ Medium (2)

Field	Comments
	○ Low (1) For Detectability, the values available are: ○ Difficult to detect 3) ○ Medium to detect (2) ○ Easy to detect (1)
Score	Enter the score for the value that you select.

Performing Risk Assessments for Clinical Trials

To perform a risk assessment for a clinical trial, you select an appropriate risk assessment template for a program, protocol, region, or site in that clinical trial. This template facilitates uniformity in the assessment process.

After you save the selected risk assessment template, a list of attributes that you must evaluate appears in the Assessment Attributes list. Attributes are frequently questions that you answer to evaluate the risk of adverse outcomes or the integrity of data for the program, protocol, region, or site. To evaluate an attribute, you enter an appropriate value for the attribute. In the Assessment Attributes list, you cannot add attributes to or delete attributes from the risk assessment template.

To perform a risk assessment for a clinical trail

1. Complete one of the following steps:
   - To perform a risk assessment of a clinical program, navigate to the Clinical Programs screen, then the Program List view and drill down on the Program field of the clinical program that you want to assess.
   - To perform a risk assessment of a clinical protocol, navigate to the Protocols screen, then the Protocol List view, and drill down on the Protocol # field of the protocol that you want to assess.
   - To perform a risk assessment of a clinical region, navigate to the Regions screen, then the Region List view, and drill down on the Region field of the region that you want to assess.
   - To perform a risk assessment of a site, navigate to the Site Management screen, then the Protocol Site List view and drill down on the Site # field of the site that you want to assess.
2. Navigate to the RACT Assessment view.
3. In the Assessment Templates list, create a new record and complete the necessary fields. Some fields are shown in the following table.

Field	Comments
Name	When you save the record, displays the name of the template that you select followed by an automatically generated number that uniquely identifies the assessment, but you can change this name.

Field	Comments
Template Name	Select a template that includes the appropriate attributes to assess the program, protocol, region, or site.
Description	Displays the description of the template that you select.
Updated	Displays the date and time that you last updated the record.
Score	Displays the sum of the Weight field multiplied by the Score field for the assessment attributes that are associated with the template. This field is populated after you assign values to assessment attributes.
Percent	Displays as a percentage the result of the Score field for the template divided by the Maximum Score field for the template. This field is populated after you assign values to assessment attributes.
Maximum Score	Displays the highest score possible for the template that you select. For each assessment attribute in the template, the Weight field is multiplied by the highest value possible in the Score field. The sum of these results is the maximum score for the template.

4. In the Assessment Questions list, enter a value for each question to assess the program, protocol, region, or site in the clinical trial. Some fields are described in the following table.

Field	Comments
Order	(Read-only) Displays the order number for the question when you save the assessment template record. Administrators set up the order number for each question when they set up the template.
Category	(Read-only) Displays the category for the question, such as Safety, Technology, Operational Complexity, and so on.
Questions	(Read-only) Displays the assessment question when you save the assessment template record. Administrators set up questions when they set up the template.
Impact	Select an impact value for the question, which can be one of the following: o High (3) o Medium (2) o Low (1)

Field	Comments
	This value determines the impact of the individual risk on the trial.
Probability	Select a probability value for the question, which can be one of the following: o High (3) o Medium (2) o Low (1) This value determines the probability of occurrence of the individual risk.
Detectability	Select a detectability value for the question, which can be one of the following: o Difficult to detect 3) o Medium to detect (2) o Easy to detect (1) The higher the detectability of individual risk, the lower the overall risk to the trial
Weight	(Read-only) Displays the weight for the attribute when you save the assessment template record. Administrators set up the weight for each attribute when they set up the template. This field is essentially ranks the importance of the category. If all categories have a default value of 1.0, then all categories are of equal importance.
Risk Score	(Read-only) Displays the risk assessment score for the individual question. Individual risk scores are calculated automatically from the values in the following fields: Impact, Probability, Detectability, Weight. The default formula for calculating individual risk score is product of Impact, Probability, Detectability and Weight.
Risk Level	Select a value that specifies the type of risk assessment template, which can be one of the following: o Program o Protocol o Program/Protocol
Rationale	If required, type in any explanatory information to capture the rationale for category risk level assessment.
Functional Impact	Select a functional impact value for the attribute, which can be one of the following: o Medical Monitoring Plan

Field	Comments
	○ Safety Plan ○ Data Plan ○ Statistical Analysis Plan ○ Monitoring Plan ○ Training Plan ○ Quality Plan ○ Risk Management Log ○ Communication Plan This field highlights the specific functional plans that might be impacted by this assessment.
Mitigation	If required, type in the mitigation actions or plans for categories with the highest category risk score.

5 Administering Clinical Subjects and Clinical Visits

Administering Clinical Subjects and Clinical Visits

This chapter covers administering clinical subjects and clinical visits. It includes the following topics:

About Subject Visit Templates

Subject visit templates allow you to set up a clinical visit schedule using the clinical protocol. The template is then used to generate screening, rescreening, and enrollment schedules for each subject, according to the subject's screening, rescreening, and enrollment dates.

If you amend the protocol, then you must create new versions of the subject visit template to reflect the modifications to the protocol.

Process of Defining Subject Visit Templates

To define a subject visit template for scheduling subject visits, perform the following tasks:

- *Creating Subject Visit Templates*
- *Defining Versions for Subject Visit Templates*
- *Defining Subject Visits*
- *Defining Planned Subject Visits*
- *Defining Activities for Subject Visits*

Creating Subject Visit Templates

This topic describes how to create a subject visit template.

This task is a step in *Process of Defining Subject Visit Templates*.

To create a subject visit template

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.
2. In the Subject Visit Templates list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Name	Type the name of the subject visit template.
Protocol #	Select the protocol for the subject visit template. Select from the list of existing protocols in the Pick Protocol dialog box.
Title	Displays the title for the protocol that you select.
Comments	Type comments about the subject visit template.

Defining Versions for Subject Visit Templates

This topic describes how to define a version for a subject visit template.

This task is a step in *Process of Defining Subject Visit Templates*.

To define a version for a subject visit template

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.
2. In the Template Versions list, create a new template version record or select a version that you created by using the Versions view.

   Some fields are described in the following table.

Field	Comments
Version	Select the version of the subject visit template.
Comments	Type comments about the version. This field has a maximum character length of 250 characters. This field is not copied when you copy the subject visit template.
Start Date	Select the date that you create the version of the subject visit template.
End Date	Select the date that you must complete the version of the subject visit template.
Status	Select the status of the version of the subject visit template. The following values are available: o In Progress o Approved o Obsolete When you create a new version of the subject visit template, the Status field is populated with a value of In Progress.
Change Summary	Type a summary of changes to the version of the subject visit template.

Defining Subject Visits

This topic describes how to define subject visits in a subject visit template.

This task is a step in *Process of Defining Subject Visit Templates*.

To define subject visits

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.
2. For the new template version record, create a visit record in the Visits list for each visit that a subject will make to the site.

   Some fields are described in the following table.

Field	Comments
Sequence	Type the sequence number of the visit. Typically, the first visit has a sequence number of 1.
Visit Type	Select the type of clinical visit. The following preconfigured values are available: o Screening o Rescreening o Enrollment o End of Study You can add, modify, or delete values for the Visit Type field.
Name	Type the name of the visit, for example, screening or baseline.
Planned	Select this field to define a subject visit as a planned visit. This field is selected by default.
Status Tracking Visit	Select this field to enable automatic tracking of the status in the Subject Status MVG (multi value group) for each visit type. You can set only one visit as the status tracking visit for each visit type. For example, if TreatmentPhase1, TreatmentPhase2, and TreatmentPhase3 clinical visits exist for a Treatment visit type, then you can set only TreatmentPhase3 as the status tracking visit. When you select the Status Tracking Visit field for a visit, the following status records are automatically created in the Subject Status MVG when each predefined visit type is processed: o A Visit Type value of Screening creates a Screened status record in the Subject Status MVG. o A Visit Type value of Re-Screening creates a Re-screened status record in the Subject Status MVG. o A Visit Type value of Enrollment creates an Enrolled status record in the Subject Status MVG. o A Visit Type value of End of Study creates a Completed status record in the Subject Status MVG. You can manually override the automatic value in the Subject Status MVG. Any create, update, or delete operations on the tracked status fields trigger automatic create, update, and delete operations in the Subject Status MVG.

Field	Comments
	Automatic status tracking is not enabled for custom values in the Visit Type list. You can edit the Status Tracking Visit field only in the subject visit template. This field is read-only when copied to the subject's visit plan. If you do not enable automatic status tracking for a clinical visit, then you can manually create, update, and delete status records in the Subject Status MVG. The following conditions apply: o You can create only one status record for each visit type. Multiple status records for the same visit type are not permitted. If Visit Type is not null, then it must be unique. o When Visit Type is null, the status value must be unique. Multiple status records with the same Status value, and a null Visit Type, are not permitted. The value pair of Visit Type and Status must be unique.
Lead	Type the lead time from the start date. You define the start date in the Schedule Date field when scheduling the subject.
Lead Units	Select the units for the lead time.
Min	Type the time before the lead time that the visit can occur. For example, if Min is 1 and Min/Max Units is days, then the visit can occur one day before the scheduled date. Do not leave this field empty.
Max	Type the time after the lead time that the visit can occur. For example, if Max is 2 and Min/Max Units is days, then the visit can occur up to two days after the scheduled visit. Do not leave this field empty.
Min/Max Units	Select the units for the Min and Max values. Do not leave this field empty.
# CRF Pages	Type the number of CRF (case report form) pages.
Status	Select the status of the visit. The following subject status values are available: o Screened

Field	Comments
	○ Screen Failure ○ Randomized ○ Enrolled ○ Completed ○ Early Terminated ○ Re-screened ○ Withdrawn The Status field is not copied when you copy the subject visit template to the subject's visit plan.

Defining Planned Subject Visits

This task describes how to define planned subject visits for the clinical trial. For example, complete this task to define whether treatment visits or surgery visits are planned for a subject.

This task is a step in *Process of Defining Subject Visit Templates*.

To define planned subject visits

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.
2. In the Visits list, define the planned subject visits using one of the following methods:
   a. To define all the subject visits as planned visits, click Plan All.
   b. To define selected subject visits as planned visits, select the Planned field for each visit.

Defining Activities for Subject Visits

This task describes how to define activities for subject visits in the clinical trial.

This task is a step in *Process of Defining Subject Visit Templates*.

To define activities for a subject visit

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.
2. For each visit record, create a set of activity records in the Activities list to describe the procedures and tasks required for the visit. Some fields are shown in the following table.

Field	Comments
Duration	Select the estimated length of time to complete the activity.

Field	Comments
Payment Flag	Select this field to indicate that you pay the investigator for this activity. This flag is selected by default. For more information about payments, see *Setting Up and Making Clinical Payments*
Payment Amount	Type the standard amount that you pay the investigator for this activity. You can adjust this amount for each site or each individual.

Approving Subject Visit Templates

Setting the status of a subject visit template to approved sets the subject visit template as read-only. You can modify only the Approved Date field of an approved subject visit template.

To approve a clinical subject visit template

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.
2. In the Template Versions list, select the version of the template to approve.
3. Enter the date in the Approval Date field.
4. Select Approved in the Status field.

About Automatic Tracking of Subject Status

This topic describes the fields that the mechanism for automatically tracking subject status uses, and the automatic operations that they trigger in the Subject Status MVG (multi value group). The Subject Status MVG contains a history of the subject's status. It contains the following fields.

- **Date.** The date that users change or update the status.
- **Status.** The status of the subject, for example, Screened, Enrolled, or Re-screened.
- **Primary.** A flag that sets the current status. This field appears in the Status field of the Subjects view.
- **Comments.** Comments about the subject status.
- **Visit Type.** The type of clinical subject visit, such as Screening or Enrollment. This field is null for status records, such as Randomized and Withdrawn.

Status Tracking Fields that Trigger Create and Delete Operations on Records in Subject Status MVG

The following table lists the status tracking fields that trigger create and delete operations on the records in the Subject Status MVG. The records in the Subject Status MVG are automatically updated as follows:

- Populating a status tracking field listed in the following table automatically creates the corresponding status record in the Subject Status MVG, including Status, Date, and Visit Type fields, where applicable
- Deleting a status tracking field listed in the following table automatically deletes the entire corresponding status record in the Subject Status MVG, including the Status, Date, and Visit Type fields, where applicable.

Status Tracking Field	Record in Subject Status MVG Automatically Created or Deleted
Random ID	Randomized
Screen Failure Reason	Screen Failure
Withdrawn Reason	Withdrawn
Early Termination Reason	Early Terminated
Missed	Missed
Completed	Status that the status value in the Visit Plans list for that visit defines
Override Status	Missed, or the status that the status value in the Visit Plans list for that visit defines

Status Tracking Fields that Trigger Update Operations on Fields of Subject Status MVG

The following table lists the status tracking fields that trigger update operations on the Date and Status fields of the Subject Status MVG. The fields of the Subject Status MVG are automatically updated as follows:

- Populating or updating a status tracking field listed in the following table automatically triggers an update to the corresponding Date or Status field value in the Subject Status MVG.
- Deleting a status tracking field listed in the following table automatically triggers a delete operation on the corresponding Date or Status field value in the Subject Status MVG.

Status Tracking Field	Field of Subject Status MVG Automatically Updated
Randomized Date	Date field in the record of the Subject Status MVG with a Status field of Randomized

Status Tracking Field	Field of Subject Status MVG Automatically Updated
Screen Failure Date	Date field in the record of the Subject Status MVG with a Status field of Screen Failure
Withdrawn Date	Date field in the record of the Subject Status MVG with a Status field of Withdrawn
Early Terminated Date	Date field in the record of the Subject Status MVG with a Status field of Early Terminated
Completed Date	Date field in the record of Subject Status MVG
Override Status	Status field in the Subject Status MVG is updated to Missed, or the status value in the Visit Plans list for that visit.

Creating Records for Clinical Subjects

CRAs (clinical research associates) can enter information about clinical subjects. When they create the subject record, the subject visit template that is active for the site is used to set up a schedule of visits and activities for the subject.

To create a record for a clinical subject

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site to which you want to add a subject.
3. Navigate to the Subjects view.
4. In the Subjects list, create a new record and complete the necessary fields. Some fields are shown in the following table.

Field	Comments
Last Completed Visit Date	Select this field to use the last completed clinical visit date for rescheduling clinical visits.
Subject ID	Type a unique identifier for the subject.
Encounter Date	Select the date that the subject first registers for the trial.
Screening #	Displays the screening number for the subject. This field is automatically generated from the Subject ID field and the Encounter Date field. The screening number is automatically generated after you enter the Subject ID field and the Encounter Date field, and save the record.
Enrollment ID	Type the principal ID number for the subject.

Field	Comments
Status	Select a record containing a history of the subject's status. This record contains values for the following fields: o **Primary.** A flag that sets the current status. This status appears in the Status field of the Subjects view. o **Visit Type.** The type of clinical subject visit, such as Screening or Enrollment. o **Status.** The status of the subject, for example, Screened, Enrolled, or Re-screened. o **Date.** The date that users change or update the status. o **Comments.** Comments about the subject's status. You can override automatic status updates.
Randomization ID	Type an ID number for the subject, which you can use in randomized studies where both an enrollment ID and a randomization ID are required.
Informed Consent Dates	Select the date that the subject signs the informed consent form for participation in the clinical trial. You must obtain informed consent prior to initiation of any clinical screening procedures.
Screen Failure Reason	Select the reason the subject fails screening.
Withdrawn Reason	Select the reason the subject withdraws from the clinical trial.
Early Termination Reason	Select the reason the subject's participation in the trial terminates early. The following values are available: o Adverse Event o Completed o Death o Lack of Efficacy o Lost to Follow-Up o Non-Compliance with Study Drug o Other o Physician Decision o Pregnancy o Progressive Disease o Protocol Violation o Recovery o Screen Failure o Study Terminated by Sponsor

Field	Comments
	○ Technical Problems ○ Withdrawal by Subject ○ Not Done

Scheduling Clinical Subjects

Scheduling a subject applies the activated subject visit template. You enter a single start date for all subject visit types in the Schedule Date field.

To schedule a clinical subject

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to schedule a subject.
3. Navigate to the Subjects view.
4. In the Subjects list, drill down on the screening number field of the subject to schedule. The Visits view of the Subjects screen appears. Some fields are described in the following table.

Field	Comments
Early Terminated Date	Displays the date that the subject's participation in the trial terminates.
Randomized Date	Displays the date that you randomize the subject into an arm of the trial.
Withdrawn Date	Displays the date that the subject withdraws from the clinical trial.
Screen Failure Date	Displays the date that the subject fails screening.

5. Click Schedule.

   The Schedule applet is launched.
6. Select a date in the Schedule Date field, and click OK.

   The subject visits record updates as follows:

   - All the visits in the active subject visit template are copied to the Visit Plans list.
   - The Visit Type, Name, Start Date, Planned, Status Tracking Visit, and Status fields are copied from the subject visit template.
   - The planned dates and due dates are calculated using the lead time in the subject visit template and the start date in the Schedule Date field. The planned dates and due dates are calculated as follows:

planned or due date equals schedule date plus lead time.

> **Note:** You can also schedule subjects through workflows. Set the Enroll Screen Rescreen Through WorkFlow user property to true to execute the schedule subject tasks in workflows instead of executing these tasks through applets and business component methods. If the Enroll Screen Rescreen Through WorkFlow user property is set to true, then workflows in other user properties are executed according to context. You can change workflow names to execute custom workflows. You can also modify other workflows and business service methods according to your needs. For more information about the Enroll Screen Rescreen Through WorkFlow user property, see *User Properties for Business Components in Siebel Clinical*.

Rescheduling Clinical Subjects

You can reschedule clinical subject visits using a fixed date, or using the delay between the Planned Date and Completed Date for the last completed visit. Select the Last Completed Visit Date field to base the rescheduling of subject visits on the date of the last completed visit, and deselect this field to base the rescheduling of subject visits on a fixed date. You can define the rescheduling mechanism at the site level. The selected rescheduling option at the subject level overrides the selected option at the site level.

To reschedule a clinical subject

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to reschedule a subject.
3. Navigate to the Subjects view.
4. Drill down on the screening number field of the subject to reschedule.

   The Visits view of the Subjects screen appears.
5. Complete one of the following steps:
   - Deselect the Last Completed Visit Date field to reschedule subject visits using a fixed date.
   - Select the Last Completed Visit Date field to reschedule subject visits using the date of the last completed visit.
6. Click Reschedule.
7. To reschedule subject visits using a fixed date, enter a date in the Reschedule applet. The subject visit dates are rescheduled as described in the following table.

Reschedule Option	Reschedule Mechanism
Fixed Date	The remaining subject visit dates are rescheduled using the date in the Reschedule applet.
Last Completed Visit Date	The remaining subject visit dates are rescheduled using the delay between Planed Date and Completed Date for the last completed visit. The rescheduled dates for the planned dates and due sates are calculated as follows:

Reschedule Option	Reschedule Mechanism
	Planned or Due Date equals Planned Date or Due Date plus Delay

Administering Subject Visits in Batch Mode

The Visit Types view displays the subject visit plan by visit type. Each distinct visit type for the subject appears in the Visit Types applet, with a read-only field indicating whether or not each visit type is planned for the subject. Associated visits for each visit type appear for batch administration, and associated activities for each visit also appear. The Visit Types view provides for the following administration tasks:

- Viewing clinical visit types for each subject, the associated visits, and the associated activities.
- Planning and unplanning clinical visits in batch mode, by visit type.
- Deleting clinical visits in batch mode, by visit type.

To administer subject visits in batch mode

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to administer visits.
3. Navigate to the Subjects view.
4. In the Subjects list, drill down on the screening number field of the subject for which you want to administer visits.
5. The Visits view of the Subjects screen appears.
6. Navigate to the Visit Types view.
7. The visit types, associated visit plans, and associated activities appear.
8. Complete one of the following steps:
    - To plan all visits associated with a visit type, select the visit type, and click Plan.
    - To unplan all visits associated with a visit type, select the visit type, and click Unplan.
    - To delete a visit type and all associated visit plans, select the visit type, and click Delete Visits.

Screening Clinical Subjects

You can schedule screening visits when the subject signs the informed consent form. The Subject Status MVG (multi value group) is automatically updated for the screening visit that is the status tracking visit in the subject visit template.

To screen a clinical subject

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to screen a subject.
3. Navigate to the Subjects view.

4. In the Subjects list, enter the informed consent date for the subject to screen as follows:
    - Click the select button in the Informed Consent Dates field to open the Informed Consent Dates dialog box.
    - Select the appropriate version.
    - Enter an informed consent date for the subject, and click OK.
5. In the Subjects list, drill down on the screening number field of the subject.

   The Visits view of the Subjects screen appears.
6. (Optional) Edit subject visit dates or activities.

   For example, you might want to edit some subject visit dates so that visits are not scheduled on weekends. If the rescheduled date is outside the range that the subject visit template specifies, then a warning message appears, but *the visit is still rescheduled* according to the new date.
7. Select the Completed field for the screening visit in the Visit Plans list.
8. Enter the completion date in the Completed Date field.

   If the subject clinical visit is a status tracking milestone visit, then the subject record automatically updates as follows:
    - A record with a value of Screening in the Visit Type field is added to the Subject Status MVG.
    - The Status field is updated to Screened.
    - The Date field of the Subject Status MVG is populated with the date in the Completed Date field of the Visit Plans list.

Rescreening Clinical Subjects

You can rescreen a subject who initially fails screening. You must define the Re-screening visit type in the visit plan for the subject. The Subject Status MVG (multi value group) is automatically updated for the re-screening visit that is the status tracking visit in the subject visit template.

To rescreen a clinical subject

1. Navigate to the Subjects screen.
2. Drill down on the screening number field of the subject who failed screening.
3. Navigate to the Visits view.
4. (Optional) Edit subject visit dates or activities.
5. Select the Completed field for the Re-screening visit in the Visit Plans list.
6. Enter the completion date in the Completed Date field.

   If the subject clinical visit is a status tracking milestone visit, then the Subject record automatically updates as follows:
    - A record with a value of Re-screening in the Visit Type field is added to the Subject Status MVG.
    - The Status field is updated to Re-screened.
    - The Data field of the Subject Status MVG is populated with the date in the Completed Date field of the Visit Plans list.

Enrolling Clinical Subjects

You enroll in the study a subject who successfully passes screening or rescreening. The Subject Status MVG (multi value group) is automatically updated for the enrollment visit that is the status tracking visit in the subject visit template.

To enroll a clinical subject

1. Navigate to the Subjects screen.
2. Drill down on the screening number field for the subject to enroll.
3. Navigate to the Visits view.
4. (Optional) Edit subject visit dates or activities.
5. Enter the enrollment ID in the Subjects applet.
6. In the Visit Plans list, complete the following steps:
   a. Select the Completed field for the enrollment visit.
   b. Enter the completion date in the Completed Date field.

      If the subject clinical visit is a status tracking milestone visit, then the Subject record automatically updates as follows:

      - A record with a value of Enrollment in the Visit Type field is added to the Subject Status MVG.
      - The Status field is updated to Enrolled.
      - The Date field of the Subject Status MVG is populated with the date in the Completed Date field of the Visit Plans list.

Randomizing Clinical Subjects

This topic describes how to randomize a subject for a randomized clinical trial.

To randomize a clinical subject

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to randomize a subject.
3. Navigate to the Subjects view.
4. In the Subjects list, drill down on the screening number field of the subject to randomize.

   The Visits view of the Subjects screen appears.
5. Complete the necessary fields as shown in the following table.

Field	Comments
Random ID	Type the ID number assigned to the subject for the randomized trial.
Randomized Date	Select the date that you randomize the subject into an arm of the trial.

Field	Comments

6. Save the record.

   The Subject record automatically updates as follows:
   - A Randomized status record is added to the Subject Status MVG (multi value group), and the value in the Randomized Date field is copied to the Date field of the Subject Status MVG.
   - The Status field is updated to Randomized.

Overriding Initial Subject Status

You can override the initial subject status for a status tracking clinical visit by selecting a new status in the Override Status field. For example, for a status tracking clinical visit with a Missed value, you can subsequently set the Override Status field to Completed.

When you select the Completed value from the Override Status field, the previous Missed value is updated to the status value for that visit in the Visit Plans list. For example, the status value for the Screening visit type is updated to Screened.

When you select the Missed value in the Override Status field, the previous status record for that visit is updated to Missed.

To override initial subject status

1. Navigate to the Subjects screen.
2. Drill down on the screening number field for the subject.
3. Navigate to the Visits view.
4. Select one of the following values from the Override Status field:
   - Completed
   - Missed
5. For a completed visit, enter the completion date in the Completed Date field.

Transferring Clinical Subjects

The subject transfer feature allows you to manage the transfer of subjects from one study site to another, with options to retain the subject's visit data and also the destination study site's visit template. During subject transfers, the payment exceptions from the destination site are applied and the payment data is recalculated. A history of all subject transfers is tracked at the subject and the site level. To ensure more robust data audit trails, you can no longer delete subjects and sites.

To transfer clinical subjects

1. Navigate to the Subjects screen, then the Subject List view.

2. In the Subject list, select the subject that you want to transfer.
3. Click Transfer to open the Transfer applet.
4. In the Transfer applet, complete the fields as shown in the following table.

Field	Description
Site	Select the destination site to which you want to transfer the subject. Only sites within the same protocol are included in the Sites drop-down list.
Informed Consent Date	Select an informed consent date if prompted.
Scheduled Date	The start date for the destination site's clinical subject visits.
Reason	Select a reason for the subject transfer from the Reason drop-down list.
Comments	Type in any comments about the subject transfer as required.
Transfer Date	The date of the subject transfer.

5. If the destination site's Subject Visit Template version differs from the originating site, then you are prompted with a message similar to the following:

   `Would you like to delete uncompleted visits from the old version and completed visits from the new version?`

   Click OK to confirm the deletion of non applicable visits.

   After confirmation, the subject transfer process completes, new visits and payment exceptions are applied as defined by the destination site, and the transfer history for the subject and the site is updated accordingly. For more information, see *Viewing Subject Transfer Information for Clinical Subjects and Sites*.

Viewing Subject Transfer Information for Clinical Subjects and Sites

The Transfer History and Subject Transfer History views show all the subject transfer information for subjects and sites respectively.

To view subject transfer information for clinical subjects and sites

1. View the subject transfer information for a subject as follows:
   a. Navigate to the Site Management screen, then the Protocol Site List view.
   b. Drill down on the Site # field of the site that you want.

c. Navigate to the Subjects view.
d. Drill down on the Screening # field of the subject for which you want to view subject transfer information.

   The Visits view of the Subjects screen appears showing the Visit Plans.
e. Navigate to the Transfer History view.

   The Transfer History view appears showing all subject transfers against the subject. The view includes the following information for each subject transfer: Source Site Name, Destination Site Name, Transfer Date, Transferred By, Status at Transfer, Description.

2. View the subject transfer information for a site as follows:

   a. Navigate to the Site Management screen, then the Protocol Site List view.
   b. Drill down on the Site # field of the site for which you want to view subject transfer information.
   c. Navigate to the Subject Transfer History view.

      The Subject Transfer History view appears showing all subject transfers against the site as follows:

      - The Subject In applet lists all subject visits transferred to the site.
      - The Subject Out applet lists all subject visits transferred from the site.

Viewing Subject Visits Information for Sites

The Subjects Visits view shows information about all the completed subject visits for a site, including any completed subject visits where the subject has been transferred to another site.

To view subject visits information for sites

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. Drill down on the Site # field of the site for which you want to view subject visits.
3. Navigate to the Subjects Visits view.

   The Subjects Visits view appears showing all completed subject visits (including subject visits where the subject has been transferred to another site) and corresponding activity information for the selected site.

Creating Unscheduled Subject Visits

On occasion, you might have to create an unscheduled subject visit.

Creating a Subject Visit From the Subjects Screen

Complete the procedure in this topic to create a subject visit from the Subjects screen.

To create a subject visit from the Subjects screen

1. Navigate to the Subjects screen, then the Subject List view.

2. In the Subject list, drill down on the screening number field of the subject for whom you want to add an unscheduled visit.
3. Navigate to the Visits view.
4. In the Visit Plans list, create a new record and complete the necessary fields.

   The type of the visit is automatically populated with Unscheduled Visit.

Creating a Subject Visit From the Calendars for Sites

Complete the procedure in this topic to create a subject visit from the calendar for a site.

To create a subject visit from the calendar for a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to add subject visits.
3. Navigate to the Calendar view.
4. Create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Done	Select the date that the visit occurred.
Done Flag	Select this field to indicate that the visit occurred.
Calendar Planned	Select the date and time that the subject visit is due. This field value is automatically populated in the Due field.
Lock Assignment	Select this field as necessary. If the activity is locked, then Assignment Manager cannot access it. If it is unlocked, then Assignment Manager can reassign it.
Assigned To	Select the user ID of the person assigned to the subject visit.

Terminating Clinical Trials Early for Clinical Subjects

On occasion, you might have to terminate a subject's participation in a trial before completion of the trial. For example, the subject might no longer want to take part in the trial, or the subject might fail a screening.

To terminate a clinical trial early for a clinical subject

1. Navigate to the Subjects screen, then the Subject List view.

2. In the Subject list, drill down on the screening number field of the subject of the trial you want to terminate.
3. Enter the reason for terminating the subject's trial using one of the following methods:
    - To indicate that the subject failed the screening, enter the reason in the Screen Failure Reason field.
    - To indicate that the subject withdrew from the trial, enter the reason in the Withdrawn Reason field.
    - To indicate that the subject's trial terminated early, select the reason in the Early Termination Reason field.
4. Enter the date for terminating the subject's trial using one of the following methods:
    - To indicate that the subject failed the screening, enter the date in the Screen Failure Date field.
    - To indicate that the subject withdrew from the trial, enter the date in the Withdrawn Date field.
    - To indicate that the subject's trial terminated early, enter the date in the Early Terminated Date field.
5. Save the record.

Subject Termination Event	Automatic Field Updates
Screen Failure	The Subject record automatically updates as follows: • A record with a Status field value of Screen Failure is added to the Subject Status MVG (multi value group), and the value in the Screen Failure Date field is copied to the Date field of the Subject Status MVG. • The Status field is updated to Screen Failure.
Early Terminated	The Subject record automatically updates as follows: • A record with a Status field value of Early Terminated is added to the Subject Status MVG, and the value in the Early Terminated Date field is copied to the Date field of the Subject Status MVG. • The Status field is updated to Early Terminated.
Withdrawn	The Subject record automatically updates as follows: • A record with a Status field value of Withdrawn is added to the Subject Status MVG, and the value in the Withdrawn Date field is copied to the Date field of the Subject Status MVG. • The Status field is updated to Withdrawn.

When a Screen Failure or Early Terminated event occurs, all remaining visits for the subject are deleted. For more information, see the LS Subject Terminate Study Status Value 1 user property in *User Properties for Business Components in Siebel Clinical*.

Applying Protocol Amendments to Sites and Clinical Subjects

When you revised a protocol mid-study, apply the protocol amendments and update:

- The subject visit template version associated with the site.
- The visit schedules of any subjects who are still in the study.

Applying Revised Subject Visit Templates to Sites

This topic describes how to apply a new version of the subject visit template to a site when you revise a protocol mid-study. When you activate the new version of the subject visit template at the site, the Schedule button is enabled in the Subjects screen.

To apply a revised subject visit template to a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, select the site to which you want to apply a new version of the subject visit template.
3. In the Versions field, click the select button and complete the following steps:
   a. Select the new version of the subject visit template.
   b. Enter a date in IRB Approval Date field for the new version.
   c. Select the Active field for the new version.
   d. Click OK.

Applying Revised Subject Visit Templates to Clinical Subjects

This topic describes how to apply a new version of the subject visit template to a subject when you revise a protocol mid-study. When you activate the new version of the subject visit template at the site, the Schedule button is enabled in the Subjects screen.

To apply a revised subject visit template to a clinical subject

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to update subject visits.
3. Navigate to the Subjects view.
4. Complete one of the following steps:
   - To update the subject visit templates for all subjects at the site, click Apply Version to All.
     For all subjects at this site, except for those subjects with a Status field value of Early Terminated or Completed, the value in the Informed Consent Dates field is cleared, and the record for the new, active version of the template is selected in the dialog box for the Informed Consent Dates field.
   - To update the subject visit templates for some subjects at the site, select the subject records, and click Apply Version to Selected.
     For the selected subjects, except for those subjects with a Status field value of Early Terminated or Completed, the value in the Informed Consent Dates field is cleared, and the record for the new, active version of the template is selected in the dialog box for the Informed Consent Dates field.
5. In the Subjects list, drill down on the screening number field of the enrolled subject whose schedule you want to update for the revised subject visit template.
   The Visits view of the Subjects screen appears.
6. In the Subjects form, complete the following steps to enter the informed consent date for the new version:
   a. Click the select button in the Informed Consent field to open the Informed Consent Dates dialog box.
   b. Enter an informed consent date for the new version, and click OK.

7. Click Schedule, and complete the following steps:

    a. Enter the Schedule Date.

    A message appears asking if you want to delete uncompleted visits from the old version of the subject visit template and completed visits from the new version of the subject visit template. Non-applicable visits are those visits generated from the old template version that are scheduled to occur after the new Informed Consent Date and those visits generated by the new template version that have due dates prior to the new Informed Consent Date.

    b. Complete one of the following steps:

    - Click OK.

      The non-applicable visits are deleted.
    - Click Cancel.

      The new visits for the new protocol version are appended to the existing Visit Plans list. No visits are deleted. Typically, if you click Cancel, then you can return at a later stage to the Visits list and delete future-scheduled visits from the original version of the subject visit template and past-scheduled visits from the new version of the subject visit template.

    The Subject Visits record updates as follows:

    - All the visits in the new active subject visit template are copied to the Visit Plans list.
    - The Visit Type, Name, Start Date, Planned, Status Tracking Visit, and Status fields are copied from the subject visit template.
    - The planned dates and due dates are calculated using the lead time in the subject visit template and the start date in the Schedule Date field. The planned dates and due dates are calculated as follows:

      planned or due date equals schedule date plus lead time.

    For more information, see *Rules for Applying Protocol Amendments*.

Rules for Applying Protocol Amendments

If you choose Cancel in response to the delete uncompleted visits from the old version and completed visits from the new version dialog, then a new set of visits is created and added to the visits already created from prior versions.

If you choose OK, then a new set of visits is created, the two sets of visits are compared, and the non-applicable visits are deleted when the following conditions are satisfied:

1. The subject Informed Consent date is used for the new version as a cut-off date for transitioning from the old version to the new version.
2. Equivalent Visits are those visits that have the same Visit Name.
3. For an old visit (created from the old template version) with a Completed date:

    a. If the Completed date is earlier than the Informed Consent date, then the old completed visit remains intact, and the corresponding visit from the more recent amended version is deleted. In other words, visits under the old version that are completed before an amendment takes effect are preserved, and the equivalent visits from the new version are deleted.

    b. If the Completed date is later than or equal to the Informed Consent date, then the following rules apply:

- If the Due date of the corresponding new visit is earlier than the Informed Consent date, then the old completed visit remains intact. In other words, visits that are scheduled under the old version to complete before an amendment occurs but are actually completed later are also preserved. The equivalent visits from the new version are deleted.
- If the Due date of the corresponding new visit is later than or equal to the Informed Consent date, then the visits from the old version are deleted, but the completed dates are copied to the equivalent visits from the new version. In addition, all child activities of the completed visits are set to Completed and have the same completed date of the parent visit. This rule applies in situations where the subject already switched to the new version before Siebel Clinical is setup in time to handle such a scenario. In such a case, the visit records generated under the old version are marked Complete instead of the visits from the new version.

4. For an old clinical visit without a Completed date:
    a. If the Due date is later than or equal to the Informed Consent date, then the visit generated from the old version of the subject visit template is deleted. In other words, future visits generated from the old version that are not yet completed are deleted, and their equivalent visits from the new version are preserved.
    b. If the Due date is earlier than the Informed Consent date, then the visit from the old version remains intact. In other words, visits under the old version that are not completed (these visits are presumably the visits that a Subject missed in the past) are preserved, and the equivalent visit from the new version is deleted.
5. For a new visit generated under the new template version:
    a. If the Due date is earlier than the Informed Consent date, then the new visit is deleted.
    b. If the Due date is later than or equal to the Informed Consent date, then the new visit remains intact, although it might still be deleted using the aforementioned rules.

Rules for Deleting Subject Visits When Deemed Non-Applicable by Early Termination

In addition to automatically deleting non-applicable visits for protocol amendments, visits that are scheduled and deemed non-applicable by early termination are deleted. Visits that are not scheduled through a template are not deleted. The following rules apply to deleting the appropriate visits:

1. Delete non-applicable, scheduled visits after a subject terminates the study.

    When the Status field of a subject is changed to Early Terminated and the Early Terminated date is populated, all future visits are deleted. Future visits are visits with a Due date and an Early Terminated date.
2. Delete non-applicable, scheduled visits after a subject fails screening.

    When the Status field of a subject is changed to Screen Failure and the Screen Failure date is populated, all future visits are deleted. Future visits are visits with a Due date and a Screen Failure date.

About Rolling Up Information for Subject Enrollment

Siebel Clinical supports clinical organizations in better managing subject enrollment for their trials in real-time. To implement this tracking, subject information is rolled up from the site level to the region level and then to the protocol

level or directly from the site level to the protocol level. However, frequently this data is not available to the clinical organization, which presents significant business challenges.

For example, if organizations out source trials to CROs (clinical research organizations), then the clinical organizations cannot always receive subject level information. The enhanced subject rollup functionality provides accurate subject enrollment data at the region and protocol level, when subject level information is not available for each site or region.

Characteristics of Trials Where Subject Level Data is Available for Each Site

Trials, for which subject level information is available for each site, display the following rollup characteristics:

- Subject enrollment information is automatically rolled up from the subject level to the site level, from the subject level to the region level, and from the subject level to the protocol level.
- When a subject is the first subject to enroll for a site, region, or protocol, the date in the First Subject Enrolled field for that site, region, or protocol, is automatically populated.
- When a subject is the last subject to complete or drop off the trial for the site, region, or protocol, the date in the Last Subject Off Study field for that site, region or protocol is automatically populated.

  When you terminate a site by entering a date in the Site Termination field, the date in the Last Subject Off Study field for the site is populated with the latest date in the Completed Date field or the Early Terminated Date field of all subjects that are associated with the site. Siebel Clinical verifies that the date in the Last Subject Off Study field is later than or equal to the date in the First Subject Enrollment field. For more information, see the Last Subject Off Study Date Rollup Status n user property in *User Properties for Business Components in Siebel Clinical*.

  Also, the Last Subject Off Study date is automatically rolled up from the site level to the region level and from the site level to the protocol level. For more information, see the Date RollUp Fields:Region n user property and the Date RollUp Fields:Protocol n user property in *User Properties for Business Components in Siebel Clinical*.

Characteristics of Trials Where Subject Level Data is Not Available for Each Site

Trials, for which subject level information is not available for a site, display the following characteristics:

- You can select the No Subject Info field for sites that do not have subject level information.
- CRAs (clinical research associates) can enter information in the following fields for sites that do not have subject or site level information:
  - # Screened
  - # Re-Screened
  - # Screen Failure
  - # Enrolled
  - # Completed
  - # Early Terminated
  - First Subject Enrolled

    - Last Subject Off Study
    - Initiated Date
    - Terminated Date
- Information that you manually for sites without subject data is rolled up in the same manner as the information for sites with subject data.

Characteristics of Trials Where Site Level Data is Not Available for a Region

Trials, for which site level information is not available for a region, display the following characteristics:

- The No Site Info field is selected for regions that do not have site level information. You do not have to select the No Subject Info field.
- CRAs (clinical research associates) can enter information in the following fields for regions that do not have site level information:
    - # Screened
    - # Re-Screened
    - # Screen Failure
    - # Enrolled
    - # Completed
    - # Early Terminated
    - First Subject Enrolled
    - Last Subject Off Study
    - Initiated Date
    - Terminated Date
    - First Site Initiated Date
    - Last Site Terminated Date
- Information that you manually for regions without site data is rolled up in the same manner as the information for regions with subject data.

Viewing Status Accruals for Clinical Subjects of Sites

Clinical subject data is automatically rolled up to the clinical site record. The Status Field RollUp user properties determine the criteria for the automatic rollup of subject status accruals to the clinical site record. For more information about these user properties, see *User Properties for Business Components in Siebel Clinical*.

You must select the Status Tracking Visit field (in the Visits list in the Visit Templates view of the Administration - Clinical screen) to automatically create subject status accruals for pairs of a visit type value and a subject status value. For more information about the Status Tracking Visit field, see *Defining Subject Visits*.

The task in this topic describes how to view subject status accruals for each visit type and subject status of a clinical site.

To view status accruals for clinical subjects of a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to view subject accruals.
3. Navigate to the Subject Status Accruals view.

   Some fields are described in the following table.

Field	Comments
Visit Type	Displays a type of clinical subject visit that is associated with the site, such as Screening, Re-screening, or Enrollment.
Status	Displays a subject status that is associated with the site, such as Screened, Re-screened, or Enrolled.
Total Accrual Number	Displays the number of site subjects for which the value in the Visit Type field and the value in the Status field currently apply to the subjects and for which these same values applied to the subjects in the past.
Current Accrual Number	Displays the number of site subjects for which the value in the Visit Type field and the value in the Status field currently apply to the subjects. The value in the Visit Type field and the value in the Status field currently apply to records in the Subject Status MVG (multi value group) for which the Primary field is selected. You see the Subject Status MVG when you click the select button in the Status field of the subject record.

Viewing Status Accruals for Clinical Subjects of Clinical Regions

Clinical subject data is automatically rolled up to the clinical region record. The Status RollUp Fields: Region user properties determine the criteria for the automatic rollup of subject status accruals to the clinical region record. For more information about these user properties, see *User Properties for Business Components in Siebel Clinical*.

You must select the Status Tracking Visit field (in the Visits list in the Visit Templates view of the Administration - Clinical screen) to automatically create subject status accruals for pairs of a visit type value and a subject status value. For more information about the Status Tracking Visit field, see *Defining Subject Visits*.

The task in this topic describes how to view subject status accruals for each visit type and subject status of a clinical region.

To view status accruals for clinical subjects of a clinical region

1. Navigate to the Regions screen, then the Region List view.
2. In the Region list, drill down on the Region field of the region for which you want to view subject accruals.
3. Navigate to the Subject Status Accruals view.

   Some fields are described in the following table.

Field	Comments
Visit Type	Displays a type of clinical subject visit that is associated with the region, such as Screening, Re-screening, or Enrollment.
Status	Displays a subject status that is associated with the region, such as Screened, Re-screened, or Enrolled.
Total Accrual Number	Displays the number of region subjects for which the value in the Visit Type field and the value in the Status field currently apply to the subjects and for which these same values applied to the subjects in the past.
Current Accrual Number	Displays the number of region subjects for which the value in the Visit Type field and the value in the Status field currently apply to the subjects. The value in the Visit Type field and the value in the Status field currently apply to records in the Subject Status MVG (multi value group) for which the Primary field is selected. You see the Subject Status MVG when you click the select button in the Status field of the subject record.

Viewing Status Accruals for Clinical Subjects of Clinical Protocols

Clinical subject data is automatically rolled up to the clinical protocol record. The Status RollUp Fields: Protocol user properties determine the criteria for the automatic rollup of subject status accruals to the clinical protocol record. For more information about these user properties, see *User Properties for Business Components in Siebel Clinical*.

You must select the Status Tracking Visit field (in the Visits list in the Visit Templates view of the Administration - Clinical screen) to automatically create subject status accruals for pairs of a visit type value and a subject status value. For more information about the Status Tracking Visit field, see *Defining Subject Visits*.

The task in this topic describes how to view subject status accruals for each visit type and subject status of a clinical protocol.

To view status accruals for clinical subjects of a clinical protocol

1. Navigate to the Protocols screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol for which you want to view subject accruals.
3. Navigate to the Subject Status Accruals view.

   Some fields are described in the following table.

Field	Comments
Visit Type	Displays a type of clinical subject visit that is associated with the protocol, such as Screening, Re-screening, or Enrollment.
Status	Displays a subject status that is associated with the protocol, such as Screened, Re-screened, or Enrolled.
Total Accrual Number	Displays the number of protocol subjects for which the value in the Visit Type field and the value in the Status field currently apply to the subjects and for which these same values applied to the subjects in the past.
Current Accrual Number	Displays the number of protocol subjects for which the value in the Visit Type field and the value in the Status field currently apply to the subjects. The value in the Visit Type field and the value in the Status field currently apply to records in the Subject Status MVG (multi value group) for which the Primary field is selected. You see the Subject Status MVG when you click the select button in the Status field of the subject record.

Monitoring Rates for Subject Enrollment

The Subject Status feature in the Charts view provides a graphical representation of subject enrollment rates. You can display the charts by protocol, region, or site, and in a variety of pie chart and bar chart formats.

To monitor rates for subject enrollment

1. Navigate to the Protocols, Regions, or Site Management screen.
2. In the list, select the record for which you want to create the charts.
3. Navigate to the Charts view.
4. Select values from the drop-down lists as follows:

a. From the first drop-down list, select Subject Status.
b. From the second drop-down list, select Subject Enrollment Rates.
c. From the third drop-down list, select the time frame.
d. From the fourth drop-down list, select the display type, such as bar chart or pie chart.

5. Click Go.

Monitoring Status Accruals for Clinical Subjects by Visit Type

The Subject Status Analysis feature in the Charts view provides a graphical representation of subject status accruals by visit type. You can display the charts by protocol, region, or site, and in a variety of pie chart and bar chart formats.

To monitor status accruals for clinical subjects by visit type

1. Navigate to the Protocols, Regions, or Site Management screen.
2. In the list, select the record for which you want to create the charts.
3. Navigate to the Charts view.
4. Select values from the drop-down lists as follows:
   a. From the first drop-down list, select Subject Status Analysis.
   b. From the second drop-down list, select Subject Accruals.
   c. From the third drop-down list, select the time frame.
   d. From the fourth drop-down list, select the display type, such as bar chart or pie chart.
5. Click Go.

Using Audit Trail for Changes to Subject Status

The Status Audit Trail view provides a detailed history of the changes to Subject Status records, including the dates and times of the changes and details of the users who make the changes.

To use the audit trail for changes to subject status

1. Navigate to the Subjects screen, then the Subject List view.
2. In the Subject list, drill down on the screening number field of the subject.
3. Navigate to the Status Audit Trail view.

   Some fields are described in the following table.

Field	Comments
Employee Login	Displays the username of the user who changed the record.

Field	Comments
Business Component	Displays the business component for the record where the database change occurred.
Field	Displays the name of the field where the change occurred.
Operation	Displays the type of operation that was performed, for example, New Record, or Modify.
Old Value	Displays the value in the field before the database change occurred.
New Value	Displays the value in the field after the database change occurred.
Date	Displays the timestamp of the change.
Record ID	Displays the unique identifier of the record that was changed.
Base Table	Displays the name of the primary database table where the database change occurred.
Column	Displays the name of the column in which the change occurred.
Group ID	Displays the unique identifier of the group to which the user who changed the record belongs.
Node	Displays the name of the database table node where the change occurred.
Table	Displays the name of table to which the selected field belongs in the Siebel database.
Row ID	Displays the unique identifier of the row in which the change occurred.
Employee ID	Displays the unique identifier of the user who changed the record.

Generating Oracle BI Publisher Reports for Site Enrollment Status

You can integrate Siebel Clinical with Oracle Business Intelligence Publisher (BI Publisher) to generate reports. You can generate, view, and schedule preconfigured Oracle BI Publisher reports in Siebel Clinical. The preconfigured Site Enrollment Status report applies clinical trials. For more information about using Siebel Reports, and integrating with Oracle BI Publisher, see *Siebel Reports Guide* .

To generate an Oracle BI Publisher report for the site enrollment status

1. Navigate to the Protocols screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol for which you want to generate an Oracle BI Publisher report.
3. Navigate to the Sites view.
4. On the application toolbar, click Reports.
5. In the Run Report pane, complete the appropriate fields as shown in the following table.

Field	Comments
Report Name	Select the Site Enrollment Status report.
Output Type	Select the output type for the report.

6. Click Submit.

   The report runs.
7. Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

   A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals Guide* .

6 Managing Sites and Contacts for Clinical Trials

Managing Sites and Contacts for Clinical Trials

This chapter describes how to manage sites and contacts for clinical trials. It includes the following topics:

About Managing Sites and Contacts for Clinical Trials

This chapter describes the tasks that the administrator and end users perform to update and maintain information about:

- Sites for clinical trials
- Contacts (investigators and other site personnel)
- Accounts (hospitals and clinics where you carry out the trials)
- Employees on the site team
- Regulatory documentation relevant to recording the trials
- Contracts associated with individual sites

Siebel Adverse Events and Complaints Management feature set allows you to record the relationships among these six entities.

This chapter also describes setting up and using:

- Activity plans for sites
- Account and contact assessments

Scenario for Managing Sites and Contacts for Clinical Trials

This topic gives one example of how to manage sites and contacts for clinical trials. You might manage sites and contacts for clinical trials differently, depending on your business model.

To prepare for the clinical trial, the administrator sets up templates to generate activity plans for site initiation and to track documents. The administrator also creates templates that the CRA (clinical research associate) uses near the end of the trial to assess contacts and accounts associated with the trial. The administrator might have to update contact and account information before the CRA can begin work on the site. Another important task that the administrator might have to complete is to associate contracts with a site. Often, the administrator might have to associate multiple contracts with individual sites.

When the CRAs begin work on a new clinical trial, they must set up a number of site visits that dictate whether the site can carry out the trial. Then they add new information and update existing information about accounts, contacts, and sites, and about the affiliations and associations among them. Maintaining accurate data is critical to successful clinical trials.

When creating a new contact record, the CRAs request that the administrator enter the contact's primary specialty. The CRAs cannot enter data in this field. Then the CRAs must appoint a team of employees to assign to that site so that the study manager can keep track of the members of each site team.

The CRAs plan how to carry out the protocol at the site by creating an activity plan for the site. This plan determines how to conduct the trial. The CRAs use the clinical protocol site template that the administrator creates. They also track any number of extra documents that are associated with a site. These documents can include regulatory or clinical trial documentation.

From time to time, the CRAs enter account or contact records incorrectly, or they discover that some account or contact records are obsolete. The CRA then puts in a request to the administrator to delete those accounts and contacts. The CRAs do not have the permissions to delete these records.

Before the clinical trial ends, the administrator or the study manager creates a contact assessment template that each CRA can use to evaluate the performance of the investigators at the conclusion of the trial.

CAUTION: In some countries, it is not permitted to evaluate the performance of site personnel. Obtain legal advice before using the contact assessment feature in Siebel Clinical.

Process of Managing Sites and Contacts for Clinical Trials

This topic details sample tasks that administrators and end users often perform when managing site (including satellite site) and contact information. Your company might follow a different process according to its business requirements.

Perform the administrative tasks described in this topic before performing the related end-user tasks. For example, a clinical protocol site template must exist before you can create the corresponding activity plan for the site.

For information about creating a site for a clinical trail, see *Creating Sites for Clinical Trials*. For information about creating a satellite site for a clinical trial, see *Creating Satellite Sites for Clinical Trials*.

Administrator Procedures

The following list shows the tasks administrators typically perform to manage site and contact information:

- *Creating Clinical Protocol Site Templates*. An administrator creates templates that detail the activities that users must perform at all sites that carry out the same protocol.
- *Creating Contact and Account Assessment Templates*. An administrator or the study manager creates assessment templates that define weighted attributes for assessing a contact or account.
- *Maintaining Contacts and Accounts*. An administrator maintains records of contact license numbers, and deletes erroneous or obsolete account and contact data.
- *Associating Contracts with Sites*. An administrator or a study manager enters details about the contracts for a site and the payment details for each contract.
- *Associating Accounts with Contracts*. An administrator or a study manager enters details about the accounts for a site.
- *Associating Accounts with Sites*. An administrator applies the accounts for protocols and regions to site records.
- *Associating Activities with Sites*. An administrator applies the activities for protocols and regions to site records.
- *Associating Documents with Sites*. An administrator applies the documents for protocols and regions to site records.

End-User Procedures

The following list shows the tasks end users typically perform to manage site and contact information:

- *Creating and Managing Site Visits*. CRAs (clinical research associates) create site visits to evaluate, initiate, monitor, and close out sites.
- *Managing Contacts for Sites*. Users can associate sites with contacts, archive contact records for sites, and view the history of contacts at sites.
- *Adding Address Types for Sites*. Users can add a specific type of addresses for each site.
- *Assigning Employees to Site Teams*. Managers or CRAs add employees to the team associated with the site.
- *Creating Activity Plans for Sites*. CRAs use the clinical protocol site template that an administrator creates to plan a list of activities for each site.
- *Applying Activity Templates to Sites*. Users can simultaneously apply one or multiple activity templates to one or multiple sites for a study.
- *Tracking and Adding Documents at Sites*. CRAs and regional study managers post clinical trial and regulatory documentation for review at the site, region, and protocol levels.
- *Creating Activities for Document Tracking*. CRAs attach and track documents at the protocol, region, and site levels, or for accounts or contacts.
- *Managing Tracking Activities for Case Report Forms*. Users can create tracking activities for CRFs (case report forms).
- *Tracking Case Report Forms*. Users can create and track CRFs as part of a protocol, site, and region.
- *Creating Correspondence Activities for Sites*. Users can track all correspondence (phone, fax, email, and letters that the postal service delivers) between a site and a study team member as correspondence activities for the site.
- *Adding Notes to Sites*. Users can add notes to a site.
- *Viewing the Status History for Sites*. Users can view the changes to the Status field for a site.
- *Assessing Contacts and Accounts*. CRAs evaluate contacts and accounts by using the attributes in an assessment template.
- *Generating Oracle BI Publisher Reports for Document Tracking*. Users can generate, view, and schedule preconfigured Oracle BI Publisher reports in Siebel Clinical.
- *Generating Reports for Actual Visits*. Users can generate a report for completed clinical subject visits.
- *Generating Reports for Planned and Actual Dates of Subject Visits*. Users can generate a report for completed clinical subject visit dates.

Managing Satellite Sites and Contacts for Clinical Trials

You manage satellite sites and contacts for clinical trials in the same way that you manage normal sites and contacts for clinical trials. For more information, see the following topics:

- *Process of Managing Sites and Contacts for Clinical Trials*.
- For information about creating a site for a clinical trail, see *Creating Sites for Clinical Trials*.
- For information about creating a satellite site for a clinical trail, see *Creating Satellite Sites for Clinical Trials*.

Satellite sites function in a similar way to normal sites. From a business perspective, it is important to track all the satellite sites for a parent site and ensure that the protocol guidelines are being followed at the satellite as defined for the parent site. Other important issues to note before starting to create and manage satellite sites for clinical trials include the following:

- A site can have multiple satellite sites, but each satellite site can have only one parent site.
- If a subject visit happens at a site, then all corresponding activities also happen at the same site.
- All roll up and roll down of information in the standard hierarchy for the parent site (Protocol - Region - Site) applies for the satellite site. This includes the roll up and roll down of the following information: position, payment, subject status, and contract amount.6-5
- Bulk actions carried out at the protocol and region level for the parent site (such as activity, account, document tracking, and payment generation) apply for the satellite site.
- The following data is consolidated from the parent site to the satellite site: subject enrolment, accrual payment, contract amount, and payment amount.
- The satellite site and parent site can be of different types. For example, even if the parent site is a Hospital and the satellite site is a Private Clinic, the same principal investigator conducts the study for both sites.
- The satellite site inherits the parent site's subject visit template version, principal investigator, team, and currency information by default. Any change in the subject visit template version, principal investigator, team, or currency information is rolled down from the parent site to the satellite.
- The subject enrollment of data from the satellite site is rolled up to the parent site.
- The payments and contract data from the satellite site is rolled up to the parent site.
- The following use cases are supported for satellite sites:
    - A subject is allocated to a satellite site and carries out all visits at the satellite site as part of the study.
    - A subject is allocated to a parent site and carries out some visits at the satellite site as part of the study.

Creating Clinical Protocol Site Templates

Activities can be associated directly with sites. For example, all sites carrying out the same protocol perform similar activities for site initiation, and submit similar documents to the regulatory agencies. When many activities are common to multiple sites, the clinical protocol site template helps CRAs (clinical research associates) create activities for the sites.

To create a clinical protocol site template, create an activity template with a Type field of Clinical Protocol Site. Make sure that Protocol Title field is complete and correct. For information about how to create activity templates, see *Siebel Applications Administration Guide* .

If an activity template with a Type field of Clinical Protocol Site is not associated with a protocol title, then users can apply the template to all sites in the Activity Plans view of the Site Management screen. If an activity template with a Type field of Clinical Protocol Site is associated with a protocol title, then users can apply the activity template only to the sites associated with the protocol.

> **Note:** Unlike trip report templates, clinical protocol site templates are protocol-specific. To use a clinical protocol site template for more than one protocol, either duplicate the record, and then edit the Protocol Title field, or delete the protocol title to make the template available to all sites.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

Creating Contact and Account Assessment Templates

The purpose of the assessment is to determine a single total score or a percentage that you can use to rank a contact or account. For information about creating an assessment template, see *Siebel Applications Administration Guide* .

For contact assessment templates, set the template type to Contact. For account assessment templates, set the template type to Account.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

Maintaining Contacts and Accounts

The end users are responsible for much of the day-to-day maintenance of their contact and account data. For information about managing contacts and accounts, see *Siebel Life Sciences Guide* .

However, the administrator is responsible for the following tasks:

- Entering data into the primary specialty field for contacts.
- Deleting contact and account records that are in error or are obsolete.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

Associating Contracts with Sites

You can associate the contracts defining the total site payments with each site. Some sites might need only one contract that governs the entire payment for the site. However, you might have to associate multiple contracts with a site. Each contract can have multiple payees. You can associate multiple contracts and multiple payees with a site.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

To associate a contract with a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site with which you want to associate a contract.
3. Navigate to the Contracts view.
4. In the Contracts list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Contract #	Displays the number assigned to this contract. This field is automatically populated.
Type	Select the type of contract to associate with the site.

Field	Comments
Contract Amount	Type the amount of money that the contract is worth. If you enter multiple contracts, then the total value of all contract amounts equals the total contract amount for the site. This total appears in the Contract Amount field on the site form.
Payee Last Name	Select the name of the person who receives payments for the contract. You can enter multiple payees for the contract by using the multi-value picklist.
Address	Select the address associated with the payee.

Associating Accounts with Contracts

This topic describes how to associate accounts with a contract for clinical site. You can associate multiple accounts with a contract by adding them to the selected list in the Accounts MVG (multi value group). Set one account as the primary account. The first account that you add to the Accounts MVG is set as the primary account by default. You can change the primary account by selecting the Primary field in the Accounts MVG.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

To associate an account with a contract

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site.
3. Navigate to the Contracts view.
4. Click the select button in the Account field to open the Accounts dialog box, and complete the following steps:
   a. Move the record for an available account to the list of selected accounts.

      The first account that you associate with the contract is the primary account by default.
   b. Configure the primary account for the contract by selecting the Primary field.
   c. Click OK.

Associating Accounts with Sites

You can associate the accounts for a clinical protocol and for a clinical region with sites.

After you complete this task, the account records appear in the Accounts view in the Protocol Site List view of the Site Management screen. The account records originate in the Accounts view in the Protocol List view of the Protocols screen or in the Accounts view in the Region List view of the Regions screen. In these Accounts views, you can change the field values in the account records.

The Account field and the Type field uniquely identify an account record for a site. You can associate an account for a clinical protocol or for a clinical region with a site only if the values in these two fields do not already exist for an account record associated with the site. Consequently, note the following:

- If you change the value in either of these fields for an account record, and then reassociate that account record with the site, then a new account record is created for the site.
- If you change other field values for an account record, and then reassociate that account record with the site, then a new account record is not created for the site, and the field values for the existing account record for the site do not change.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

Associating Accounts for Clinical Protocols with Sites

The Accounts view of the Protocols screen is automatically populated with the account records that administrators set up in the Accounts view in the Protocol List view of the Administration - Clinical screen. Also, you can manually add other account records to the Accounts view of the Protocols screen.You can associate the account records in this view with specific sites.

To associate the accounts for a clinical protocol with sites

1. Navigate to the Protocols screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol for which you want to associate accounts with sites.
3. Navigate to the Accounts view.
4. Select the accounts that you want to associate with sites.
5. Click Apply To Sites.
6. In the dialog box of site records applicable to the protocol, select the appropriate sites, and click OK.

Associating Accounts for Clinical Regions with Sites

The Accounts view of the Regions screen is automatically populated with the account records that administrators set up in the Accounts view in the Region List view of the Administration - Clinical screen. Also, you can manually add other account records to the Accounts view of the Regions screen.You can associate the account records in this view with specific sites.

To associate the accounts for a clinical region with sites

1. Navigate to the Regions screen, then the Region List view.
2. In the Region list, drill down on the Region field of the region for which you want to associate accounts with sites.
3. Navigate to the Accounts view.
4. Select the accounts that you want to associate with sites.
5. Click Apply To Sites.
6. In the dialog box of site records applicable to the region, select the appropriate sites, and click OK.

Associating Activities with Sites

You can associate activities for a clinical protocol and for a clinical region with sites.

After you complete this task, the activity records appear in the Activities view in the Protocol Site List view of the Site Management screen. The activity records originate in the Activities view in the Protocol List view of the Protocols screen or in the Activities view in the Region List view of the Regions screen. In these Activities views, you can change the field values in the activity records.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

Associating Activities for Clinical Protocols with Sites

You can associate activity records for a clinical protocol with specific sites.

Each time you click the Apply To Sites button in the procedure in this topic, new activity records for the selected sites appear in the Activities view in the Protocol Site List view of the Site Management screen. These new activity records contain any changed field values in the originating activity records in the Activities view in the Protocol List view of the Protocols screen.

Also, these new activity records have no values in the First Name field and Last Name field, and not the values in these same fields in the originating activity records, because you must manually add the contacts who are associated with a site in the activity records for the site.

To associate the activities for a clinical protocol with sites

1. Navigate to the Protocols screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol for which you want to associate activities with sites.
3. Navigate to the Activities view.
4. Select the activities that you want to associate with sites.
5. Click Apply To Sites.
6. In the dialog box of site records applicable to the protocol, select the appropriate sites, and click OK.

Associating Activities for Clinical Regions with Sites

You can associate activity records for a clinical region with specific sites.

Each time you click the Apply To Sites button in the procedure in this topic, new activity records for the selected sites appear in the Activities view in the Protocol Site List view of the Site Management screen. These new activity records contain any changed field values in the originating activity records in the Activities view in the Region List view of the Regions screen.

Also, these new activity records have no values in the First Name field and Last Name field, and not the values in these same fields in the originating activity records, because you must manually add the contacts who are associated with a site in the activity records for the site.

To associate the activities for a clinical region with sites

1. Navigate to the Regions screen, then the Region List view.
2. In the Region list, drill down on the Region field of the region for which you want to associate activities with sites.
3. Navigate to the Activities view.
4. Select the activities that you want to associate with sites.
5. Click Apply To Sites.
6. In the dialog box of site records applicable to the region, select the appropriate sites, and click OK.

Associating Documents with Sites

You can associate documents for a clinical protocol and for a clinical region with sites.

After you complete this task, the document records appear in the Document Tracking view in the Protocol Site List view of the Site Management screen. The document records originate in the Document Tracking view in the Protocol List view of the Protocols screen or in the Document Tracking view in the Region List view of the Regions screen. In these Document Tracking views, you can change the field values in the document records.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

Associating Documents for Clinical Protocols with Sites

You can associate document records for a clinical protocol with specific sites.

Each time you click the Apply To Sites button in the procedure in this topic, new document records for the selected sites appear in the Document Tracking view in the Protocol Site List view of the Site Management screen. These new document records contain any changed field values in the originating document records in the Document Tracking view in the Protocol List view of the Protocols screen.

To associate the documents for a clinical protocol with sites

1. Navigate to the Protocols screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol for which you want to associate documents with sites.
3. Navigate to the Document Tracking view.
4. Select the documents that you want to associate with sites.
5. Click Apply To Sites.
6. In the dialog box of site records applicable to the protocol, select the appropriate sites, and click OK.

Associating Documents for Clinical Regions with Sites

You can associate document records for a clinical region with specific sites.

Each time you click the Apply To Sites button in the procedure in this topic, new document records for the selected sites appear in the Document Tracking view in the Protocol Site List view of the Site Management screen. These new document records contain any changed field values in the originating document records in the Document Tracking view in the Region List view of the Regions screen.

To associate the documents for a clinical region with sites

1. Navigate to the Regions screen, then the Region List view.
2. In the Region list, drill down on the Region field of the region for which you want to associate documents with sites.
3. Navigate to the Document Tracking view.
4. Select the documents that you want to associate with sites.
5. Click Apply To Sites.
6. In the dialog box of site records applicable to the region, select the appropriate sites, and click OK.

Creating and Managing Site Visits

CRAs (clinical research associates) typically carry out the following types of visits to a site:

- **Site evaluation.** A site visit to evaluate a site's qualification for a study
- **Site initiation.** A site visit to initiate a site
- **Site monitoring.** A site visit to monitor study progress and to monitor and retrieve CRFs (case report forms)
- **Site close-out.** A site visit to close out or terminate a site at the conclusion of a study
- **Unscheduled.** (Optional) An unexpected site visit that a CRA can carry out

CRAs create these visits for each site for which they are responsible. When a CRA creates a site visit, it appears in the CRA's calendar, the site investigator's calendar, and the study manager's calendar. Consequently, the study manager can keep track of all site visits for all CRAs. The calendar entry is a useful reminder for investigators of scheduled site visits.

You create site visits using the Protocol Site List view of the Site Management screen. From this view, CRAs can view all their site visits and all follow-up activities that arise from the visits. You can also view all site visits and follow-up activities associated with these visits. Study managers can also filter site visits to see the visits that are assigned to their teams, and view follow-up activities to assess the most pressing issues.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

To create a site visit

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field for the site with which you want to create a visit.
3. Navigate to the Site Visits view.
4. Create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Visit Name	Type a descriptive name for the visit.
Visit Start	Select the date and time that the visit is due to occur. When you drill down on this field, you see the trip report for the visit.
Visit Status	Select the status of the site visit.

Field	Comments
Trip Report Completed	Select the date that the trip report for this visit is complete.
Trip Report Status	Select the status of the trip report. The following values are available: o Not Started o In Progress o Completed o Submitted o Approved o Rejected A preconfigured state model allows for a structured state transition. For more information about trip reports, see *Administering and Using Clinical Trip Reports*
Assigned To	Select the user ID of the person assigned to the site visit.

Monitoring Site Visits Using the Calendar

You can monitor all CRA (clinical research associate) visits to a site from the Calendar view. Use the calendar to view visits on a daily, weekly, or monthly basis.

Managing Contacts for Sites

A contact is a person working at a clinical site. Contacts include investigators, typically medical professionals who are also researchers, and site coordinators, who might be the practicing nurses administering the treatment plan according to the clinical protocol.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

Associating Sites with Contacts

A record for the contact that you select in the PI Last Name field of the site record is automatically created in the Contacts view of the site. This record is automatically populated with a value of Principle Investigator in the Role field. You can associate the site with additional contacts.

To associate a site with a contact

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site that you want to associate with a contact.
3. Navigate to the Contacts view.

4. In the Current list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Role	Select the role of the contact. The Principle Investigator value for this field is automatically populated for the principle investigator of the site. In the Contacts view, you cannot change this value, or assign this value to another contact. To change the principle investigator for the site, you change the value in the PI Last Name field of the form for the site record.
Last Name	Select the last name of the contact. When you click the select button in this field, the Pick Contacts dialog box appears. Click the Affiliated Contacts button in this dialog box to view only those contacts who are affiliated with the account for the site. After you populate this field, you cannot change its value.
Start Date	Select the date that the contact record is effective. You can select a past date, but not a future date.

Archiving Contact Records for Sites

Instead of deleting inactive contact records, you archive these records so that you can view the history of contact records for the site. You cannot delete contact records for sites. When you archive an inactive contact record, you move the record from the Current view for site contacts to the History view for site contacts.

To archive the contact records for a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to archive contact records.
3. Navigate to the Contacts view.
4. Select one or more contact records to archive.
5. Click Archive, and complete the following steps:
   a. In the Archive dialog box that appears, select the date that the contact record is inactive.
      You can select a past date, but not a future date.
   b. Click OK.
      The contact record is moved from the Current view for site contacts to the History view for site contacts, and the date that you select appears in the End Date field of the History view.

Viewing the History of Contacts at Sites

If you change the value in the Role field for a site contact to assign a new role to the contact, then the contact record with the prior Role field value is automatically moved to the History view for the site contact. However, if you change the

value in another field for a site contact, then the contact record with the prior field value is not automatically moved to this History view.

When you archive an inactive contact record, the record from the Current view for site contacts is automatically moved to the History view for site contacts.

To view the history of contacts at a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to view the history of contacts.
3. Navigate to the Contacts view.

   The Current list of contacts for the site appears.
4. Navigate to the History view to see the history of contacts.

   Some fields are described in the following table.

Field	Comments
Start Date	Displays the date that the contact record is effective.
End Date	Displays the date that the contact record is archived.

Adding Address Types for Sites

Users can add a specific type of addresses for each site.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

To add an address type for a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to add an address type.
3. Navigate to the Addresses view.
4. In the Addresses list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Description	Type a description for the address.
Address Type	Select an address type from the list of values to associate with the site.
Address Line 1	Select the appropriate site location from the MVG (multi value group).

Field	Comments

Assigning Employees to Site Teams

CRAs (clinical research associates) assign employees to the site team. You can roll up the team members and make them visible at the region and protocol levels.

Note: If the CRA is working from a mobile Web client, then the administrator must set up position rollup on the Web client. For more information, see *Setting Up Mobile Web Clients for Position Rollup*.

Before you can add an employee to the site team, an administrator must set up the employee record. For more information, see *Siebel Security Guide* .

You can also automatically assign an employee to the site team using the Position Rollup button or Position Rolldown button. For more information, see *Automatically Assigning Team Members Using the Position Rollup and Rolldown Buttons*. For more information about removing employees from the site team, see *About Removing Team Members From the Team of a Site*.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

To assign employees to the site team

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, select the site to which you want to add employees.
3. Edit the Team field of the site record.

   The employees are added to the site team. You also roll up the employees to the region and protocol levels.

Creating Activity Plans for Sites

An activity plan for a site is a list of activities and documents associated with the site.

Although you can create activities without a template, using a clinical protocol site template as described in this topic makes creating activities for sites more efficient. For more information, see *Creating Clinical Protocol Site Templates*.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

To create an activity plan for a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site to which you want to assign activities.
3. Navigate to the Activity Plans view.
4. In the Activity Plans list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Planned Start	Select the date and time to start the activity plan. Make sure that this date is correct before you choose a template. The due dates for the template-generated activities are based on this start date and on the lead time in the template.
Template	Select the template for the activity plan. Only templates with a type of Clinical Protocol Site and with a protocol that matches the protocol at the site are available for selection. Only activities with type of Document or Site-Initiation appear in the document tracking views.
Lock Assignment	Select this field as necessary. If the activity is locked, then Assignment Manager cannot access it. If it is unlocked, then Assignment Manager can reassign it.

5. Edit the activities in the Activities list as shown in the following table, or create more activities.

Note: To view additional fields in this list, click Menu (the cogwheel icon) and select Columns Displayed.

Field	Comments
Expected Date	Select the expected date for the activity. For document tracking, this field denotes date that the site is expected to return the signed document.
Sent Date	Select the sent date for the activity. For document tracking, this field denotes the date that you send the document to the site.
Received Date	Select the received date for the activity. For document tracking, this field denotes the date that the site returns the signed document.
Expiration Date	Select the expiration date for the activity. When you enter a date in this field, the Status field is automatically set to Done.
Status	Select the status of the activity. When you set this field to Done, the Completed Date field is automatically set to the current date.
Suppress Calendar	Select this field to indicate that the activity does not appear on the user's calendar.

Applying Activity Templates to Sites

You can simultaneously apply one or multiple activity templates to one or multiple sites for a study. Activity records with a type of Document and Site-Initiation appear in the Document Tracking view of the Site Management screen. Activity records with a type of Correspondence appear in the Activities view of the Site Management screen.

The applied templates also appear in the Activity Plans view of the Site Management screen for each of the selected sites.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

Applying Activity Templates to Sites in a Region

Complete the procedure in this topic to simultaneously apply one or multiple activity templates to multiple sites in a region.

To simultaneously apply one or multiple activity templates to multiple sites in a region

1. Navigate to the Regions screen, then the Region List view.
2. In the Region list, drill down on the Region field of the region to which you want to apply an activity template.
3. In the Sites view, select the sites to which you want to apply an activity template.
4. Click Apply Template.
5. From the Templates dialog, select one or multiple activity templates that you want to apply to the selected site, and click OK.

Applying Activity Templates to Sites in a Protocol

Complete the procedure in this topic to simultaneously apply one or multiple activity templates to multiple sites in a protocol.

To simultaneously apply one or multiple activity templates to multiple sites in a protocol

1. Navigate to the Protocols screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol to which you want to apply an activity template.
3. Navigate to the Sites view.
4. In the Sites list, select the sites to which you want to apply an activity template.
5. Click Apply Template.
6. From the Templates dialog, select one or multiple activity templates that you want to apply to the selected site, and click OK.

Tracking and Adding Documents at Sites

During a clinical trial, CRAs (clinical research associates) collect and track numerous documents, including critical regulatory documents. CRAs can take advantage of the activity plans to generate a list of documents for tracking. In the document tracking views, they can also create their own lists of activities to track important dates.

> **Note:** Regional study managers can use similar procedures to add and track documents at the region level in the Regions screen.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

Tracking Documentation Milestones

Complete the procedure in this topic to track documentation milestones.

To track documentation milestones

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to track documentation.
3. Navigate to the Document Tracking view.

   A list of documents associated with the clinical trial appears.
4. Query for the appropriate document and complete the necessary fields as shown in the following table.

Field	Comments
Activity	Displays a value of Document by default.
Name	Type the name of the document. This field is a hypertext link to the Attachments view.
Sent Date	Select the date that you send the document to the site.
Expected Date	Select the date that the site is expected to return the signed document.
Received Date	Select the date that the site returns the signed document.
Expiration Date	Select the date that the document expires.
Assigned To	Select the user ID of person assigned responsibility for the document.

Field	Comments
Lock Assignment	Select this field as necessary. If the activity is locked, then Assignment Manager cannot access it. If it is unlocked, then Assignment Manager can reassign it.

Adding Documents to Sites

Complete the procedure in this topic to add a document to a site.

To add a document to a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to track documentation.
3. Navigate to the Document Tracking view.

   A list of documents associated with the clinical trial appears.
4. Create a new record and complete the necessary fields.
5. Step off the record you just added and drill down on the Name field.

   The Attachments view appears.
6. Create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Type	Displays the type of attachment.
Auto Update.	Select this field if you want to automatically update the file during synchronization. Synchronization applies only to local files. If a file is not local, then it is not updated during synchronization.

Creating Activities for Document Tracking

Users collect numerous documents during clinical trials, either as electronic files or as paper. You must track and periodically update these documents. You can associate documents with sites, regions, protocols, contacts, or accounts.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

To create an activity for document tracking

1. Navigate to the Document Tracking screen.

2. In the Document Tracking list, create a new record and complete the necessary fields as shown in the following table.

> **Note:** You can associate an activity for document tracking with only one of the available tracking levels or entities.

Field	Comments
Name	Type the document name. In the Document Tracking list, you can click the link in this field to navigate to the associated Attachments view.
Site #, Region, Protocol, Contact, or Account.	Select a value in one of these five fields to assign the activity for document tracking to one of these five levels. In the Document Tracking list, you can click the link the selected field to navigate to the Activities view.

Reviewing, Updating, and Adding Existing Documents for Tracking

Complete the procedure in this topic to review, update, and add existing documents for tracking.

Alternatively, you can create and review activities for document tracking in the Document Tracking view for a site. Similarly, you can create activities for document tracking at the protocol and region levels in the Document Tracking view for the protocol and region.

To review, update, and add existing documents for tracking

1. Navigate to the Document Tracking screen.
2. In the Document Tracking list, query for the document you want to update.
3. Drill down on the Name field of the document.

   The associated Attachment view appears.
4. In the Attachment list, query for the document and drill down on the Name field of the document.
5. Open, update, and save the document.
6. Use the thread bar to return to the document record on the Document Tracking list.
7. Copy the original document record and revise the associated site number, Region, Protocol, Contact, or Account field.

Managing Tracking Activities for Case Report Forms

Users collect numerous CRFs (case report forms) during clinical trials, either as electronic files or as paper. You must track and periodically update these forms. You can associate CRFs with sites, regions, or protocols.

In addition to subject visit records, CRF tracking records are created when you apply a subject visit template.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

Viewing Tracking Activities for Case Report Forms

Complete the procedure in this topic to view tracking activities for CRFs (case report forms).

To view tracking activities for a case report form

- Navigate to the Document Tracking screen, then the CRF Tracking view.

  The CRF Tracking list displays all of the tracking records.

  Note: You can associate a tracking activity for a CRF with only one of the available tracking levels or entities.

  Some fields are described in the following table.

Field	Comments
Name	Displays the name of the subject visit for which you collect CRFs.
Protocol #, Region, or site #	Displays the protocol, region, or site assigned to CRF tracking.

Updating Existing Case Report Forms for Tracking

Complete the procedure in this topic to update existing CRFs (case report forms) for tracking.

Alternatively, you can update activities for CRF tracking from the CRF Tracking view of a site. Similarly, at the protocol and region levels, you can update activities for CRF tracking from the CRF Tracking view.

To update existing case report forms for tracking

1. Navigate to the Document Tracking screen, then the CRF Tracking view.
2. In the CRF Tracking list, query for the record you want to update.
3. Update and save the record.
4. You can revise the associated site number, Region, and protocol number field.

Tracking Case Report Forms

Users can track CRFs (case report forms) as part of a protocol, site, and region. They capture relevant information for each CRF record within a protocol, site and region. This information includes whether the CRFs are source verified, retrieved from a site, received in-house, or received by a data management process.

When you apply a subject visit template, in addition to creating subject visit records and the child activity records that exist in the current product, a duplicate set of visit records with a Type of Case Report Form are created (with the number of pages that the template specifies). These visit records with the number of CRF pages appear in the CRF Tracking view in the Protocol Site List view of the Site Management screen.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

To track case report forms

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to track CRFs.
3. Navigate to the CRF Tracking view
4. In the CRF Tracking list, complete the necessary fields as shown in the following table.

Field	Comments
Activity	Select the activity associated with the site.
Activity Type	Displays the activity type for the CRF. Only activity records with this activity type appear in this view.
# CRF Pages	Type the number of pages in the CRF.
Retrieved	Select this field if the CRF is retrieved.
Retrieved Date	Select the date and time that the CRF is retrieved.
Received in House	Select the date and time that the CRA (clinical research associate) receives the CRF in house.
Received by Data Management	Select the date and time that a data management process receives the CRF.
Source Verified	Select this field if the CRF is a verified source document.
Source Verified Date	Select the date and time that the CRF is source verified.

Field	Comments
Comments	Type relevant comments about the CRF.

Creating Correspondence Activities for Sites

You can track all correspondence (phone, fax, email, and letters that the postal service delivers) between a site and a study team member as correspondence activities for the site. You can create such activities for multiple sites. This feature provides an easy way to capture all forms of communication between a site and an employee, or between business partners, such as a CRO (clinical research organization) or central laboratory.

For each created correspondence activity, you create an activity record in the Activities view of the Contacts screen for each of the contacts.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

Creating Correspondence Activities for Sites

Complete the procedure in this topic to create a correspondence activity for a site.

To create a correspondence activity for a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to create a correspondence activity.
3. Navigate to the Activities view.
4. In the Activities list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Activity	Displays a value of Correspondence by default.
Activity Type	Select an activity type. The following values are available: o Case Report Form o Email o Fax o Mail o Phone
Description	Type a brief description for the correspondence activity.
Screen #	Displays the number of screens for the correspondence.

Field	Comments
Comments	Type relevant comments about the correspondence activity.
Last Name	Select the last name of the creator of the correspondence activity. This field is a required.

Creating New Role Correspondence for Sites

Complete the procedure in this topic to create a new role correspondence for a site.

To create a new role correspondence for a site

1. Navigate to the Protocols screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol for which you want to create a new role.
3. Navigate to the Sites view
4. In the Sites list, select one or multiple sites to which you want to apply a new role for the correspondence.
5. Click New Correspondence.
6. From the Roles of Contacts dialog box, select the role or multi-select the roles that best describe the individual's role, and click OK.

Creating Partner Correspondence Activities

You can track all correspondence (phone, fax, email, and letters that the postal service delivers) between business partners, such as a CRO (clinical research organization) or central laboratory.

To create partner correspondence activities

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to create a partner correspondence activity.
3. Navigate to the Activities view.
4. In the Activities list, create a new record and complete the necessary fields.

Adding Notes to Sites

When you work with site records, you often find that you want to make notes. In the Notes view, you can enter public notes or private notes. Use the link bar in the Notes view to switch between public and private notes. Anyone who can access the record can see a public note. Only the person who creates the note can see a private note.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

To add a note to a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to add a note.
3. Navigate to the Notes view, then the Private Notes view or Public Notes view.
4. Create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Created By Name	Displays your user ID.
Created Date	Displays the system date.
Note Type	Select the type of note. Examples include Exclusion, Pre-existing Condition, Permanent, System, Temporary, Business Description, Regional Plans, and Contracts Process.
Note	Type the note text.

5. Click Check Spelling to make sure your note has no spelling errors.

Viewing the Status History for Sites

For each site, you can view information about how the Status field changed in the past.

To view the status history for a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to view the status history.
3. Navigate to the Status History view.

   Some fields are described in the following table.

Field	Comments
Old Status	Displays the prior value in the Status field for the site record.
New Status	Displays the new value in the Status field for the site record.
Date	Displays the date and time that the prior value changed to the new value.

Field	Comments
Employee Login	Displays the ID of the user who changed the Status field for the site record.

Assessing Contacts and Accounts

Assessments allow end users to calculate a single numerical value that expresses the fitness of a contact or account, according to a set of attributes in the assessment template. For example, you can assess an investigator to determine competence to carry out a large scale clinical trial in phase III, or you can assess a hospital to determine suitability to carry out a similar trial. The results of this assessment help CRAs (clinical research associates) find suitable investigators and hospitals for subsequent trials. For more information, see *Creating Contact and Account Assessment Templates*.

Note: The score values in the Assessment Attributes list and the (total) score value in the Assessments list are automatically updated.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

To assess a contact or account

1. Complete one of the following steps, depending on whether you want to assess a contact or account:
    - Navigate to the Contacts screen, then the Contacts List view, and in the Contacts list, drill down on the Last Name field of the contact that you want to assess.
    - Navigate to the Accounts screen, then the Accounts List view, and in the Accounts list, drill down on the Name field of the account that you want to assess.
2. Navigate to the Assessments view.
3. In the Assessments list, create a new record.
4. In the Template Name field, select the assessment template.

    For more information, see *Creating Contact and Account Assessment Templates*.

    The other fields in the record are populated when the record is saved.
5. In the Assessment Attributes list, for each attribute:
    a. Select a value in the Value field of the attribute.
    b. Add or edit comments in the Comment field of the attribute.

Generating Oracle BI Publisher Reports for Document Tracking

You can integrate Siebel Clinical with Oracle Business Intelligence Publisher (BI Publisher) for generating reports. You can generate, view, and schedule preconfigured Oracle BI Publisher reports in Siebel Clinical. For more information about using Siebel Reports and integrating with Oracle BI Publisher, see *Siebel Reports Guide* .

The following preconfigured reports apply to clinical document tracking:

- Site Document Tracking
- Protocol Level Document Tracking
- Region Level Document Tracking
- Protocol Document Tracking Across Sites
- Regional Document Tracking Across Sites

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

Generating Reports for Site Document Tracking

This topic describes how to generate the preconfigured Site Document Tracking report for Oracle BI Publisher.

To generate a report for site document tracking

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to generate an Oracle BI Publisher report.
3. Navigate to the Document Tracking view.
4. On the application toolbar, click Reports.
5. In the Run Report pane, complete the appropriate fields as shown in the following table.

Field	Comments
Report Name	Select the Site Document Tracking report.
Output Type	Select the output type for the report.

6. Click Submit.

   The report runs.
7. Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

   A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals Guide* .

Generating Reports for Protocol Level Document Tracking

This topic describes how to generate the preconfigured Protocol Level Document Tracking report for Oracle BI Publisher.

To generate a report for protocol level document tracking

1. Navigate to the Protocols screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol for which you want to generate an Oracle BI Publisher report.
3. Navigate to the Document Tracking view.
4. On the application toolbar, click Reports.
5. In the Run Report pane, complete the appropriate fields as shown in the following table.

Field	Comments
Report Name	Select the Protocol Level Document Tracking report.
Output Type	Select the output type for the report.

6. Click Submit.

   The report runs.
7. Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

   A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals Guide* .

Generating Reports for Region Level Document Tracking

This topic describes how to generate the preconfigured Region Level Document Tracking report for Oracle BI Publisher.

To generate a report for region level document tracking

1. Navigate to the Regions screen, then the Region List view.
2. In the Region list, drill down on the Region field of the region for which you want to generate an Oracle BI Publisher report.
3. Navigate to the Document Tracking view.
4. On the application toolbar, click Reports.
5. In the Run Report pane, complete the appropriate fields as shown in the following table.

Field	Comments
Report Name	Select the Region Level Document Tracking report.

Field	Comments
Output Type	Select the output type for the report.

6. Click Submit.

   The report runs.
7. Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

   A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals Guide* .

Generating Reports for Protocol Document Tracking Across Sites

This topic describes how to generate the preconfigured Protocol Document Tracking Across Sites report for Oracle BI Publisher.

To generate a report for protocol document tracking across sites

1. Navigate to the Site Management screen.
2. On the application toolbar, click Reports.
3. In the Run Report pane, complete the appropriate fields as shown in the following table.

Field	Comments
Report Name	Select the Protocol Document Tracking Across Sites report.
Output Type	Select the output type for the report.

4. Click Submit.

   The report runs.
5. Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

   A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals Guide* .

Generating Reports for Regional Document Tracking Across Sites

This topic describes how to generate the preconfigured Regional Document Tracking Across Sites report for Oracle BI Publisher.

To generate a report for regional document tracking across sites

1. Navigate to the Site Management screen.

2. On the application toolbar, click Reports.
3. In the Run Report pane, complete the appropriate fields as shown in the following table

Field	Comments
Report Name	Select the Regional Document Tracking Across Sites report.
Output Type	Select the output type for the report.

4. Click Submit.
   The report runs.
5. Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.
   A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals Guide* .

Generating Reports for Actual Visits

This topic describes how to generate the preconfigured Actual Visits report for Oracle BI Publisher. This report lists the completed subject visits for a site.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

To generate a report for actual visits

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to generate an Oracle BI Publisher report.
3. On the application toolbar, click Reports.
4. In the Run Report pane, complete the appropriate fields as shown in the following table.

Field	Comments
Report Name	Select the Actual Visits report.
Output Type	Select the output type for the report.

5. Click Submit.
   The report runs.
6. Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.
   A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals Guide* .

Generating Reports for Planned and Actual Dates of Subject Visits

This topic describes how to generate the preconfigured Planned vs Actual Patient Dates report for Oracle BI Publisher. This report lists the planned and completed subject visit dates for a site.

This task is a step in *Process of Managing Sites and Contacts for Clinical Trials*.

To generate a report for planned and actual dates of subject visits

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to generate an Oracle BI Publisher report.
3. On the application toolbar, click Reports.
4. In the Run Report pane, complete the appropriate fields as shown in the following table.

Field	Comments
Report Name	Select the Planned vs Actual Patient Dates report.
Output Type	Select the output type for the report.

5. Click Submit.

   The report runs.
6. Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

   A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals Guide* .

7 Managing Partial Source Data Verification

Managing Partial Source Data Verification

This chapter covers how to manage partial source data verification. It includes the following topics:

About Partial Source Data Verification

To ensure that all of the data collected during the clinical trial is complete, accurate, and verifiable, companies use SDV (source data verification). This key process involves many on-site visits and verification of all the data in the CRF (case report form).

The number of clinical trials is growing, and these trials are becoming more complex. Also, regulatory agencies are more closely monitoring the drug approval process. Consequently, the cost of these trials is drastically rising, and companies and CROs (clinical research organizations) face challenges in keeping budget and time issues for trials under control. Consequently, more companies and CROs are adopting risk based monitoring for their clinical trials. Risk based monitoring moves from the traditional methods involving 100% or complete SDV to PSDV (partial source data verification). It introduces strategic on-site monitoring that is based on risks and assessments about important aspects of clinical trials.

For PSDV, you plan the SDV process by using statistical and historical information about the clinical sites and the involved personnel and about events that occur at various points in the clinical trial. This planning involves decisions at various levels of the clinical trial. Some information included in partial source verification follows:

- Percentage of CRFs to verify
- Specific CRFs to verify
- Specific pages of the CRFs to verify
- Adverse events at specific points in the clinical trial

Setting Up Partial Source Data Verification for Clinical Protocols

This topic describes how to set up PSDV (partial source data verification) for clinical protocols. You set up this verification by entering PSDV values in some fields when you create a record for a clinical protocol. These values are automatically populated in the same fields for all of the regions and sites that you associate with the clinical protocol. However, you can change these automatically populated values.

If you update the PSDV values in the fields of a clinical protocol, then the updated values are not automatically populated in the same fields of the regions and sites that are already associated with the clinical protocol. If you associate new regions and sites with the clinical protocol, then the updated values are automatically populated in the same fields of the new regions and sites.

If you update the value (from Complete to Partial) in the SDV Policy field for a site that is associated with the clinical protocol, then the PSDV values in the fields of the clinical protocol are automatically populated in the same fields of the site.

To set up partial source data verification for a clinical protocol

1. Navigate to the Administration - Clinical screen, then the Protocol List view.
2. In the Protocol list, create a new record and complete the necessary fields.

   For more information, see *Setting Up Clinical Protocols*.

   Alternatively, you can select an existing protocol record to update it.
3. In the Protocol list, drill down on the protocol number field of the protocol record.
4. Navigate to the More Info view.
5. Scroll down to the Partial Source Data Verification section and complete the PSDV fields as shown in the following table.

Field	Comments
Number of Initial Subjects	Type the number of initial subjects with CRFs (case report forms) to completely verify.
Subject Auto-Select Rate	For the total number of subjects less the number of initial subjects, type the percentage with CRFs that are part of SDV (source data verification).

Setting Up Partial Source Data Verification for Clinical Regions

This topic describes how to set up PSDV (partial source data verification) for clinical regions. You set up this verification by entering PSDV values in some fields when you create a record for a clinical region. These values are automatically populated in the same fields for all of the sites that you associate with the clinical region. However, you can change these automatically populated values.

If you update the PSDV values in the fields of a clinical region, then the updated values are not automatically populated in the same fields of the sites that are already associated with the clinical region. If you associate new sites with the clinical region, then the updated values are automatically populated in the same fields of the new sites.

If you update the value (from Complete to Partial) in the SDV Policy field for a site that is associated with the clinical region, then the PSDV values in the fields of the clinical region are automatically populated in the same fields of the site.

To set up partial source data verification for a clinical region

1. Navigate to the Administration - Clinical screen, then the Region List view.
2. In the Region list, create a new record and complete the necessary fields.
   For more information, see *Setting Up Clinical Regions*. Alternatively, you can select an existing region record to update it.
3. In the Region list, drill down on the Region field of the region record.
4. Navigate to the More Info view.
5. Scroll down to the Partial Source Data Verification section and complete the PSDV fields as shown in the following table.

Field	Comments
Number of Initial Subjects	Type the number of initial subjects with CRFs (case report forms) to completely verify.
Subject Auto-Select Rate	For the total number of subjects less the number of initial subjects, type the percentage with CRFs that are part of SDV (source data verification).

Setting Up Partial Source Data Verification for Subject Visit Templates

This topic describes how to set up PSDV (partial source data verification) for subject visit templates. You set up this verification by entering PSDV values in some fields when you create a record for a subject visit template. These values are automatically populated in the same fields for all of the CRF (case report form) tracking records that are associated with the subject visit template.

To set up partial source data verification for a subject visit template

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.
2. In the Subject Visit Templates list, create a new record and complete the necessary fields.

   For more information, see *Creating Subject Visit Templates*.

   Alternatively, you can select an existing subject visit template record.
3. Scroll down to the Template Versions list, create a new record and complete the necessary fields.

   For more information, see *Defining Versions for Subject Visit Templates*.

   Alternatively, you can select an existing version record.
4. Scroll down to the Visits list, create a new record and complete the necessary fields as shown in the following table.

   Alternatively, you can select an existing visit record to update it.

Field	Comments
SDV Required	Select this field if SDV (source data verification) is necessary for the subject visit associated with the template.
Page Numbers to Verify	Type the page numbers of the CRF that are included in PSDV. If SDV is necessary for all the CRF pages, then enter All Pages. This field provides information to CRAs (clinical research associates) when they review CRFs, and does not affect processing in Siebel Clinical Trial Management System.

Setting Up Partial Source Data Verification for Sites

This topic describes how to set up PSDV (partial source data verification) for sites. You set up this verification by entering PSDV values in some fields when you create or update a record for a site.

To set up partial source data verification for a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, create a new record and complete the necessary fields.

   For more information, see *Creating Sites for Clinical Trials*.

   Alternatively, you can select an existing site record to update it.
3. In the Protocol Site list, drill down on the site number field of the site record.
4. Navigate to the More Info view.
5. Scroll down to the Integration section and the Partial Source Data Verification section and complete the PSDV fields as shown in the following table.

Field	Comments
Use CDMS Auto-Select Rule	If you use an integrated CDMS (clinical data management system), such as Oracle Health Sciences InForm, then select this field to indicate that the PSDV fields in the site record are not used in PSDV. In this scenario, the SDV Required field for the appropriate subject records is populated from the CDMS. Clear this field to indicate that the PSDV fields in the site record are used in PSDV. When you save the record after you select this field, the SDV Policy field is automatically populated with a value of External. This field is disabled until you complete the following tasks in the designated order: a. Integrate Oracle Health Sciences InForm studies with Siebel clinical. For more information, see *Overview of Clinical Data Management System Integration*. b. Select a value in the Primary Site Address field in the Integration section. You set up selectable addresses in the Addresses view of the Site Management screen. c. Select the Activate for Synchronization field in the Integration section.
SDV Policy	Select the policy for SDV (source data verification). Valid values include Complete, Partial, and External. The default value is Complete. When the value is Complete, all of the subjects associated with the site record are part of complete SDV, and the SDV Required field in those subject records is set to Yes.
Number of Initial Subjects	Type the number of initial subjects with CRFs (case report forms) to completely verify. You can change this field only if the SDV Policy field has a value of Partial. If the protocol or region record that is associated with this site already has a value in this same field, then that value is automatically populated in this field. However, you can change this automatically populated value.
Subject Auto-Select Rate	For the total number of subjects less the number of initial subjects, type the percentage with CRFs that are part of SDV. You can change this field only if the SDV Policy field has a value of Partial. If the protocol or region record that is associated with this site already has a value in this same field, then that value is automatically populated in this field. However, you can change this automatically populated value.
Total Subjects Requiring SDV	Displays the number of subjects who are included in SDV. This field is read-only. The calculation of this field value follows: (Number of Initial Subjects) plus [(Total Subjects in the Site Pool) less (Number of Initial Subjects) times Subject Auto-Select Rate] For more information about this field, see *Recalculating Clinical Subjects Requiring Source Data Verification*.

Field	Comments
Total Subjects in Site Pool	Displays the number of subjects in the site pool. This field is read-only.

Setting Up Partial Source Data Verification for Clinical Subjects

This topic describes how to set up PSDV (partial source data verification) for clinical subjects. You set up this verification by entering PSDV values in some fields when you create or update a record for a clinical subject.

To set up partial source data verification for a clinical subject

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, create a new record and complete the necessary fields.

   For more information, see *Creating Sites for Clinical Trials*.

   Alternatively, you can select an existing site record.
3. In the Protocol Site list, drill down on the site number field of the site record.
4. Navigate to the Subjects view.
5. In the Subjects list, create a new record and complete the necessary fields as shown in the following table.

   For more information, see *Creating Records for Clinical Subjects*.

   Alternatively, you can select an existing subject record to update it.

Field	Comments
SDV Required	Displays an indication of whether SDV (source data verification) is necessary for the CRFs (case report forms) of the subject. The value in this field can change in the following ways: ○ **Manual.** You can manually change the field value. To change the field value, drill down on the screening number field of the subject record to navigate to the subject form. ○ **Site.** The field value can be automatically populated using the PSDV field values of the site record that is associated with the subject record. If the value in the SDV Policy field for the associated site record is Complete, then the SDV Required field for the subject record is Yes. If the value in the SDV Policy field for the associated site record is Partial, then the SDV Required field for the subject record can be Yes or No. The value depends on the other PSDV field values. ○ **Status.** This field can be automatically populated when a status rule set exists for the Status field of the subject record. If such a rule set exists, then this field is automatically populated with a value of Yes or No.

Field	Comments
	To set up this status rule set in Siebel Tools, enter values in the SDV Subject Status user properties of the Clinical Subject business component. For example, enter the following value in the SDV Subject Status 1 user property: `"Early Terminated","Adverse Effect","Y"`. Then enter the following value in the SDV Subject Status 2 user property: `"Screen Failure","","Y"`. In this example, if a subject terminates a study early because of an adverse effect, or if a subject fails screening, then the SDV Required field is automatically populated with a value of Yes. Set the CL Highest Preference SDV Rule system preference to determine the priority order in which to implement these 3 methods (Manual, Site, and Status) to change the SDV Required field of a subject record. For more information, see *System Preferences in Siebel Clinical*.
SDV Last Updated Source	Displays the reason for the value in the SDV Required field. This field is read-only. It can have the following values: **Site.** The value in the SDV Required field is the result of the PSDV fields of the site record that is associated with the subject record. The subject records with this value are included in the site pool. **Subject Status.** The value in the SDV Required field is the result of a status rule set for the Status field of the subject record. The subject records with this value are included in the status pool. **Manual.** The user selected the value in the SDV Required field for the subject record. The subject records with this value are included in the subject pool. **External.** The value in the SDV Required field is the result of incoming data from an integrated CDMS (clinical data management system).

Viewing Case Report Forms for Partial Source Data Verification

This topic describes how to view the CRFs (case report forms) applicable to PSDV (partial source data verification). During a site visit, CRAs (clinical research associates) do not review all CRFs and all pages on those CRFs. The field values for PSDV in the subject visit template that is associated with the site visit determine the information that appears in the PSDV fields of CRFs. The CRA restricts the review to the information in these PSDV fields.

To view the case report forms for partial source data verification

1. Complete one of the following steps:

a. Navigate to the Site Management screen, then the Protocol Site List view, and drill down on the site number field of the site record in the Protocol Site list.
b. Navigate to the Protocols screen, then the Protocol List view, and drill down on the protocol number field of the protocol record in the Protocol list.
c. Navigate to the Regions screen, then the Region List view, and drill down on the Region field of the region record in the Region list.
d. Navigate to the Document Tracking screen.

2. Navigate to the CRF Tracking view.

The PSDV fields are described in the following table.

Field	Comments
SDV Required	Displays an indication of whether SDV (source data verification) is necessary for the site visit. This field is read-only, and automatically populated from the value of the same field in the subject visit template that is associated with this CRF tracking record.
Page Numbers to Verify	Displays the page numbers of the CRF that are included in PSDV. This field is read-only, and automatically populated from the value of the same field in the subject visit template that is associated with this CRF tracking record.

Tracking Case Report Forms for Partial Source Data Verification During Site Visits

This topic describes how to track the CRFs (case report forms) for PSDV (partial source data verification) during a site visit. During a site visit, CRAs (clinical research associates) do not review all CRFs and all pages on those CRFs. The field values for PSDV in the subject visit template that is associated with the site visit determine the information that appears in the PSDV fields of CRFs. The CRA restricts the review to the information in these PSDV fields.

To track the case report forms for partial source data verification during a site visit

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to track case report forms for partial source data verification.
3. Navigate to the Case Report Forms Tracking view.
4. To add case report forms for scheduled subject visits, complete the following steps:
   a. Click Add Scheduled.
   b. Select the subject visits in the dialog box that appears.

c. Click OK.
The case report forms for selected subject visits appear in the Case Report Forms Tracking view. For a description of the PSDV fields that appear in this view, see *Viewing Case Report Forms for Partial Source Data Verification*.

5. To add case report forms for unscheduled subject visits, complete the following steps:
   a. Click Add Unscheduled.
   b. Select the subject visits in the dialog box that appears.
   c. Click OK.
   The case report forms for selected subject visits appear in the Case Report Forms Tracking view. For a description of the PSDV fields that appear in this view, see *Viewing Case Report Forms for Partial Source Data Verification*.
6. In the case report forms, complete the necessary fields as shown in the following table.

Field	Comments
Source Verified	Select this field when you verify the CRF against the source document.
Retrieved	Select this field when you retrieve the CRFs from the site.
Page Numbers Verified	Type the CRF page numbers that you verify.
Charts Reviewed Date	Select the date and time that you review the clinical charts.
Forms Signed Date	Select the date and time that you sign the CRFs.

Recalculating Clinical Subjects Requiring Source Data Verification

If you change the value in the Number of Initial Subjects field or the Subject Auto-Select Rate field of a site record, then you must recalculate the value in the Total Subjects Requiring SDV field of that site record.

If you change the number of subjects in the site pool by changing the value in the SDV Required field of the site's subject records, then you must recalculate the value in the Total Subjects Requiring SDV field of the site record. If you change the number of subjects in other pools, such as the subject pool and the status pool, then you do not have to recalculate the value in Total Subjects Requiring SDV field because these other pools are not included in the calculation of this field. For more information about pools, see *Setting Up Partial Source Data Verification for Clinical Subjects*.

To recalculate the subjects requiring source data verification

1. Navigate to the Site Management screen, then the Protocol Site List view.

2. In the Protocol Site list, drill down on the site number field of a site record.
3. Navigate to the More Info view.
4. Click Reapply Auto-Select Rate.

   If the value in the Number of Initial Subjects field or the Subject Auto-Select Rate field changed, then the value in the Total Subjects Requiring SDV field is recalculated, and this recalculation considers the subjects in the site pool.

About Partial Source Data Verification for Protocol Amendments

When you change a subject visit template, you create a new version of that template. This new version results in a protocol amendment. When you apply the protocol amendment to the subjects, the following processing occurs:

1. The subject visits that are no longer valid are deleted.
2. CRF (case report form) records associated with the subject visits are deleted.
3. New subject visits are created.
4. New CRFs are created with values for PSDV (partial source data verification) fields from the latest version of the subject visit template.

   For CRFs that already have values for PSDV fields, new CRFs are also created. The values for fields that are not available in the subject visit template are copied from the prior CRFs to the new CRFs, and the values for PSDV fields are copied from latest version of the subject visit template to the new CRFs.
5. Activities are created according to the protocol amendment.

8 Setting Up and Making Clinical Payments

Setting Up and Making Clinical Payments

This chapter describes how to set up and make clinical payments. It includes the following topics:

About Setting Up and Making Clinical Payments for Subject Activities

You set and adjust payments to investigators and sites at the following levels:

- The financial administrator sets standard payment amounts through the subject visit template.
- You set exceptions to standard payment amounts according to agreements that individual sites negotiate.
- You can further adjust payments on a one-time only basis before you generate the payments.

Not all subject activities have payment amounts associated with them. For example, obtaining informed consent might be a subject activity for which you do not pay the site, but you pay a site for performing a blood test. Subject activities for which you pay the site are *payment subject activities*. (In the Siebel Clinical interface, the Payment Flag field indicates these activities.)

In addition to subject activities, you can pay sites for other activities that end users create at the site level, such as IRB (institutional review board) fees and equipment costs. End user can designate those activities as payable to the site with the Payment Flag field. For information about managing budgets at the protocol level, see *Managing Clinical Projects*.

You can use multiple currencies for a protocol. For more information about setting up currency conversions, see *Siebel Applications Administration Guide* .

You can set currencies and exchange rate dates at the following levels:

- **Protocol level.** You associate a single currency code and exchange date with a protocol record. All payments you make to sites for the protocol are converted to and rolled up in the protocol currency.
- **Region level.** If regions apply to the protocol, then set a currency code and exchange date for each region. All site payments you make in that region are converted to and rolled up in the region currency.
- **Site level.** Set a currency code and exchange date for each site. When you use a subject visit template to create subject visits and activities, all payment activities are converted to the currency for the site on the exchange date for the site.

Scenario for Clinical Payments

This topic gives one example of how clinical payments might be used. You might use payments differently, depending on your business model.

Using the input from the clinical contract or grant negotiations group, the financial administrator sets up the standard payment amounts for procedures and tasks that the site performs. A major pain-point for clinical organizations is managing investigator payments. Often organizations pay investigators for activities that they do not complete, or for activities that they complete, but not to the satisfaction of the sponsor. By specifying a withholding amount and a withholding percentage, you can withhold payments from an investigator to make sure that all activities are complete. Investigators are motivated to complete all activities so that they receive full payment.

The CRAs (clinical research associates) set up the payment exceptions for sites where different payments are negotiated for subject activities. (In some organizations, the study manager performs this task instead of the CRA.)

As the sites carry out the procedures, the financial administrator verifies successful completion of the procedures, and generates payments for these activities. He generates a payment (minus the withholding amount or percentage) when an activity is complete. If all activities for a site are complete, then he pays the investigator the full amount for all activities, including the withholding amount or percentage.

Occasionally, the sponsor or CRO (clinical research organization) must make an additional payment to a site, and the payment is not directly associated with subject activities. These payments are unplanned payments. A reimbursement for an unscheduled visit is an example of an unplanned payment.

> **Note:** As the clinical trial progresses, the sites complete the subject activities for which they are paid. Typically, personnel at the sites enter complete dates for subject activities using Siebel Site Portal. For more information about Siebel Site Portal, see *Siebel Life Sciences Portals Guide* .

Setting Up Standard Payment Amounts in Subject Visit Templates

You can set up payment amounts when you create the subject visit template. For more information, see *About Subject Visit Templates*.

Also, you can add payment amounts later by following the procedure in this topic. You can enter payments at the site level in any currency. All payment amounts at the site level are converted to the currency for the site and rolled up into the currency for the region. If a region is not applicable, then payment amounts at the site level are rolled up into the currency for the protocol.

Note: This task requires administrator privileges.

To set up standard payment amounts in the subject visit template

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.
2. Select the subject visit template and template version for which you want to add payment amounts.
3. For each visit and each activity for which to pay the sites:
   a. Select the Payment Flag field.

      If you do not select this field, then the activity does not appear in the Payment Activities view, and you cannot generate a payment.
   b. In the Payment Amount field, use the currency calculator to enter the amount and currency code.

Setting Payment Exceptions for Sites

The currency at the site might differ from the currency for the standard amount. Also, the paid amount to individual sites for a particular procedure can differ from the standard amount in the subject visit template. For more information, see *Setting Up Standard Payment Amounts in Subject Visit Templates*.

The procedure in this topic explains how to use payment exceptions to change the standard amount for a payment subject activity for an individual site. After you set the payment exception for an activity associated with the given site, visit, and template version, each time the activity is generated for a subject, the activity shows the site-specific amount.

Note: When a new subject visit template becomes active, set payment exceptions for the new template.

To set payment exceptions for a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to set up payment exceptions.
3. Navigate to the Payment Exceptions view.
4. In the Payment Exceptions list, create a new record.

   The Payment Exceptions dialog box filters payment subject activities to show only those activities for the current protocol version. However, you can query from the set of all payment subject activities with the Payment Flag field selected across all versions and protocols. Consequently, you can set payment exceptions for activities in protocol version 2 *and* in protocol version 1, for example, if you expect the site to transition to the newer version in the near future.
5. In the Payment Exceptions dialog box, select all activities for which you want to set payment exceptions, and click OK.
6. In the Exception Amount fields, enter the new amounts to pay to this site for each activity.

Note: The exception amount to pay at the site level might be in a different currency than the currency in the subject visit template or for the site. When you create subject activities at a site, the currency is converted to the currency for the site.

Splitting Payment Activities Between Multiple Payees

You can split payment activity between multiple contracts and payees. Each contract and payee combination for each payment activity split must be unique for the payment.

You define payment activity splits at the payment exceptions level in the Split Details applet. You can also define payment activity splits in the Split Details view for payments that do not have any payment exceptions. Scheduling a subject for the corresponding site applies the subject visit template, and creates a payment activity for each split payment in the Split Details applet.

To split a payment activity between multiple payees

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to set up split payments.
3. Navigate to the Payment Exceptions view.
4. In the Payment Exceptions list, select the record for which you want to create split payments.
5. Navigate to the Split Details list.
6. Create a new record for each payment split and complete the necessary fields as shown in the following table.

Field	Comments
Contract	Select the payee contract from the list of contracts. The contract and payee combination for each payment split must be unique for the payment.
Account	Displays the primary account for the selected contract.
Payee Last Name	Select the payee last name from the list. The list displays all contacts for the primary account of the selected contract.
Payee First Name	Displays the payee first name.
Split Percentage	Type the split percentage for each payment split. The total split percentage for all of the payment splits must be one hundred percent. The split percentage is automatically calculated if you manually enter the amount in the Split Amount field.

Field	Comments
Split Amount	Displays the split amount by using the split percentage of the total payment amount. You can also manually enter the amount.

7. After you create all payment splits, verify that the Split Status (icon) in the Payment Exceptions view is activated (or green in color), which indicates that the total splits for the payment amount to one hundred percent.

Copying Details for Payment Splits

You can copy the details of a split payment activity to multiple payment activities. You copy payment activity splits at the payment exceptions level.

To copy details for a payment split

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to copy split payment details.
3. Navigate to the Payment Exceptions view.
4. In the Payment Exceptions list, select the record that you want to copy.
5. Click Apply Split to Other.

   The Payment Activities Select Applet appears.
6. Select the payment activities to which you want to apply the split details, and click OK.

   The split details are created in the Split Details applet for all of the selected payment activities.
7. Navigate to the Split Details applet, and make any required amendments.

Reversing Splits for Payment Activities

This topic describes how to reverse a payment activity split. The split details for each payment are deleted from the Split Details applet.

To reverse a split for a payment activity

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to reverse payment activity splits.
3. Navigate to the Payment Exceptions view.
4. In the Payment Exceptions list, select the records that you want to reverse.
5. Click Unsplit.
6. Click OK to delete the split details for the selected payment activities.

   The split details for each selected payment activity are deleted from the Split Details applet.

Marking Subject Activities as Complete

Usually the site personnel use Siebel Site Portal to enter the date that subjects complete activities. However, a CRA (clinical research associate) can also perform this task using Siebel Clinical.

To mark subject activities as complete

1. Navigate to the Subjects screen, then the Subjects List view.
2. In the Subject list, drill down on the screening number field of the subject with complete activities.
3. Navigate to the Visits view.
4. In the Visit Plans list, select the visit that is complete, and click Complete Activities.

   The selected visit and all of its activities are marked as complete as follows:

   - The Completed field is selected.
   - The Completed Date field of all activities for the selected visit are populated with the same value in the Completed Date field of the parent visit.
   - The Status field is set to Done.
5. If necessary, edit the fields for the visit in the Activities list.

Creating Payment Activities for Sites

This task describes how to create a payment activity record for a clinical site. This record includes the contract, account, and payee details.

To create a payment activity for a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to create a payment activity.
3. Navigate to the Payment Activities view.
4. In the Payment Activities list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Payment	Select this field to define the activity as a payment activity.
Standard Amount	Type the payment amount prior to any adjustment.
Deviation Amount	Type a value in this field to adjust the value in the Actual Amount field.

Field	Comments
Actual Amount	Displays the actual amount to pay to the site. The actual amount is calculated as follows: Standard Amount plus Deviation Amount equals Actual Amount
Contract	Select the payee contract from the list of contracts.
Account	Displays the primary account for the selected contract.
Payee Last Name	Select the payee last name from the list. The list displays all primary accounts for the selected contract.
Payee First Name	Displays the payee first name.

Generating Payment Records for Sites

This topic describes how to generate payment records from payment activities. Payments are generated for each unique contract, account and payee combination for complete payment activities.

To generate a payment record for a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to generate a payment.
3. Navigate to the Payment Activities view.
4. In the Payment Activities list, select the Completed field for each payment activity to use for generating the payment record.
5. Click Generate Payment.

   The complete payments are removed from the Payment Activities list. Payment records for each unique contract, account and payee combination are generated in the Payments list.

Generating Payment Records for Sites Associated with Clinical Protocols and Regions

You can generate payment records for the sites that are associated with a clinical protocol and with a clinical region.

After you complete the payment generation task, the payment records can appear in the Payments view in the Protocol List view of the Protocols screen and in the Payments view in the Region List view of the Regions screen. Also, the payment records appear in the Payments view in the Protocol Site List view of the Site Management screen. Payment

records appear in these Payments views only if, before you start the payment generation task, complete, unpaid payment activities exist in the Payment Activities view in the Protocol Site List view of the Site Management screen.

In the Payments view in the Protocol Site List view of the Site Management screen, you can change the field values in the generated payment records. Your changes are automatically reflected in the Payments view in the Protocol List view of the Protocols screen and in the Payments view in the Region List view of the Regions screen. You cannot manually change field values in the payment records in the Payments view in the Protocol List view of the Protocols screen and in the Payments view in the Region List view of the Regions screen.

Generating Payment Records for Sites Associated with Clinical Protocols

The Payments view of the Protocols screen is automatically populated with the existing payment records for the sites that are associated with the protocol. These payment records apply to the complete payment activities for those sites. In this view, you can generate payment records for complete, unpaid payment activities for the sites in the protocol.

To generate payment records for sites associated with a clinical protocol

1. Navigate to the Protocols screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol for which you want to generate payment records for sites.
3. Navigate to the Payments view.

   If payment records exist in this view, then the selected payment record is irrelevant to this procedure.
4. Click Generate Payment.

   A dialog box of site records applicable to the protocol appears. Your system administrator can set the Popup Visibility Type property to configure the records that appear in this dialog box. For more information about this property, see *Applet Properties in Siebel Clinical*.
5. In the dialog box of site records applicable to the protocol, select the appropriate sites, and click OK.

   The complete payments are removed from the Payment Activities view in the Protocol Site List view of the Site Management screen. Payment records for each unique contract, account and payee combination are generated in the Payments view in the Protocol Site List view of the Site Management screen.

   You must again access the Payments view in the Protocol List view of the Protocols screen to view the generated payments. For the region that is associated with the selected sites, the generated payments also appear in the Payments view in the Region List view of the Regions screen.
6. (Optional) To access a notification containing details about the payment generation, click Notification on the menu toobar.

   Your system administrator can set the WF properties to configure notifications for bulk payments. For more information about these properties, see *Applet Properties in Siebel Clinical*. For more information about using notifications, see *Siebel Fundamentals Guide* .

Generating Payment Records for Sites Associated with Clinical Regions

The Payments view of the Regions screen is automatically populated with the existing payment records for the sites that are associated with the region. These payment records apply to the complete payment activities for those sites. In this view, you can generate payment records for complete, unpaid payment activities for the sites in the region.

To generate payment records for sites associated with a clinical region

1. Navigate to the Regions screen, then the Region List view.
2. In the Region list, drill down on the Region field of the region for which you want to generate payment records for sites.
3. Navigate to the Payments view.

   If payment records exist in this view, then the selected payment record is irrelevant to this procedure.
4. Click Generate Payment.

   A dialog box of site records applicable to the region appears. Your system administrator can set the Popup Visibility Type property to configure the records that appear in this dialog box. For more information about this property, see *Applet Properties in Siebel Clinical*.
5. In the dialog box of site records applicable to the region, select the appropriate sites, and click OK.

   The complete payments are removed from the Payment Activities view in the Protocol Site List view of the Site Management screen. Payment records for each unique contract, account and payee combination are generated in the Payments view in the Protocol Site List view of the Site Management screen.

   You must again access the Payments view in the Region List view of the Regions screen to view the generated payments. For the protocol that is associated with the selected sites, the generated payments also appear in the Payments view in the Protocol List view of the Protocols screen.
6. (Optional) To access a notification containing details about the payment generation, click Notification on the menu toobar.

   Your system administrator can set the WF properties to configure notifications for bulk payments. For more information about these properties, see *Applet Properties in Siebel Clinical*. For more information about using notifications, see *Siebel Fundamentals Guide* .

Generating Payment Records for Unplanned Payment Activities

You can create unplanned payments that are not associated with subject activities for clinical sites.

To generate a payment record for an unplanned payment activity

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to generate a payment.
3. Navigate to the Payment Activities view.

4. In the Payment Activities list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Completed	Select this field. When you click the Generate Payment button, the process uses only payment activity records that are complete to generate payment records.
Payment	Select this field to define the activity as a payment activity.
Standard Amount	Type the payment amount prior to any adjustment. The actual amount is calculated as follows: Standard Amount plus Deviation Amount equals Actual Amount

5. Click Generate Payment.

   The complete payments are removed from the Payment Activities list, and the payment record is created in the Payments list.
6. To complete the payment, follow Step 6 to Step 8 in *Adjusting Payment Amounts and Generating Payment Records for Sites*.

Adjusting Payment Amounts and Generating Payment Records for Sites

Although payments are generally set for each site, occasionally the financial administrator might want to make additional adjustments to the paid amount for a given payment activity. For more information, see *Setting Payment Exceptions for Sites*.

When the financial administrator finalizes the amounts, payments are generated for all complete payment subject activities in the currency for the site. Each payment record is given a unique identity number. You can later enter other information, such as check number, check date, and check amount, either manually or by importing the data from a back-office finance application.

Note: This task requires administrator privileges.

To adjust the payment amounts and generate payment records for a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to generate payments.
3. Navigate to the Payment Activities view.

   This view lists all scheduled payment subject activities for subjects associated with the site.
4. (Optional) Adjust the Actual Amount to pay to the site by entering a value in the Deviation Amount field.

Standard Amount plus Deviation Amount equals Actual Amount

5. Select the Completed field, and click Generate Payment.

The complete payments are removed from the Payment Activities list.

6. Navigate to the Payments view.

The payment generated in the previous step appears in the Payments list.

7. Complete the fields in the payment record as shown in the following table.

Field	Comments
Payment #	Displays a unique number for the payment.
Type	Select the type of payment. For payment subject activities that are generated from the Generate Payment button, this field is populated with a value of Interim Payments. For payment subject activities that are generated from a back office application, this field is populated with a value of Initial Payments.
Status	Select the status of the payment record, for example, To be Processed, In Progress, Processed, and so on. A preconfigured state model allows for a structured state transition.
Earned Amount	Type the sum of the actual payment amounts for the complete payment activities. The sum of all values in the Earned Amount column equals the Earned to Date value of the site.
Requested Amount	Displays the requested amount of payment for the complete payment activities at this site. This field is calculated as follows: Requested Amount equals Earned Amount times [(100 less Withholding Percentage divided by 100) less Withholding Amount]
Check Amount	Type the amount of money for the check. This amount is usually, but does not have to be, the same as the earned amount. The sum of all values in the Check Amount fields for a site equals the Paid to Date value of the site.
Check Date	Select the issue date for the check.
Check Number	Type the number of the check.

Field	Comments
VAT Amount	Type the value added tax for the site payment. The total VAT amount for all payments is rolled up to the region, protocol, and program levels, and appears in the VAT to Date field.
Contract #	Select the payee contract from the list of contracts.
Account	Displays the primary account for the contract that you select.

You can also automatically load the information from a back-office finance application.

8. (Optional) Drill down on the payment number field to view the payment activities associated with the payment.

Generating Final Payments for Sites

You can make final payments to sites when all payment activities are complete.

Note: All prior final payments to sites must be complete and up to date before you can generate new final payments.

To generate final payments for a site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to generate a payment.
3. Navigate to the Payments view.
4. Make sure that all Check Amount fields for past payments are up to date.
5. In the Payments list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Type	Select a value of Final Payment. When you set this field, the Requested Amount field for the final payment is automatically calculated as equal to the amount in the Earned to Date field for the site minus the amount in the Paid to Date field for the site.
Status	Displays a value of To Be Processed.
Check Amount	Type the amount of money for the check. This field is usually, but does not have to be, the same as the earned amount.
Check Date	Select the issue date for the check.

Field	Comments
Check Number	Type the number of the check.
VAT Amount	Type the value added tax for the site payment. The total VAT amount for all payments is rolled up to the region, protocol, and program levels, and appears in the VAT to Date field.
Contract #	Select the payee contract from the list of contracts.
Account	Displays the primary account for the contract that you select.

When you step-off and save the record, the Requested Amount field is automatically updated by subtracting the amount in the Paid to Date field for the site (that is, the amount in the Check Amount field) from the amount in the Earned to Date field for the site.

Reverting Payment Records

You can revert a payment record to modify the payment details. The Revert button is enabled when you select a single payment record with one of the following statuses:

- In Progress
- To Be Processed

The Revert button is disabled for other statuses, and if you select multiple records.

Your system administrator can modify the payment status values for which the Revert button is enabled by configuring the LS Clinical Enable Revert On Status user property in Siebel Tools. For more information about this user property, see *User Properties for Business Components in Siebel Clinical*.

A reverted payment activity record is removed from the Payments view and returned to the Payment Activities view.

To revert a payment record

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to revert a payment.
3. Navigate to the Payments view.
4. Select the payment to revert.
5. Click Revert.

   The payment records and split payment activities are updated as follows:

   - The reverted payment activity record is removed from the Payments view and returned to the Payment Activities view for further processing.

- If the payment record consists of multiple payment activities, and if you revert only some of the payment activities, then the Earned Amount and Requested Amount fields are recalculated for the Payment record.

Generating Oracle BI Publisher Reports for Clinical Payments

You can integrate Siebel Clinical with Oracle Business Intelligence Publisher (BI Publisher) to generate reports. You can generate, view, and schedule preconfigured Oracle BI Publisher reports in Siebel Clinical. The preconfigured Protocol Payments report applies to clinical payments. For more information about using Siebel Reports and integrating with Oracle BI Publisher, see *Siebel Reports Guide* .

To generate an Oracle BI Publisher report for Siebel clinical payments

1. Navigate to the Protocols screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol for which you want to generate an Oracle BI Publisher report.
3. Navigate to the Payments view.
4. On the application toolbar, click Reports.
5. In the Run Report pane, complete the appropriate fields as shown in the following table.

Field	Comments
Report Name	Select the Protocol Payments report.
Output Type	Select the output type for the report.

6. Click Submit.

   The report runs.
7. Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

   A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals Guide* .

9 Administering and Using Clinical Trip Reports

Administering and Using Clinical Trip Reports

This chapter describes how to set up and use clinical trip reports in Siebel Clinical. It includes the following topics:

About Administering and Using Clinical Trip Reports

The study managers or clinical administrators can set up templates for trip reports. The CRAs (clinical research associates) then use these templates when they create trip reports to record their visits to sites.

Advantages of using the trip reports in Siebel Clinical are:

- Trip reports are consistent across the organization and are based on GCP (good clinical practice) and SOPs (standard operating procedures).
- CRAs save time planning trips and writing trip reports.
- Managers save time reviewing trip reports.
- End users can generate a formatted, tamper-proof report for print or PDF from the trip report record.
- A central repository exists for all trip reports.

Scenario for Managing Clinical Trip Reports

This topic gives one example of how to manage clinical trip reports. You might manage clinical trip reports differently, depending on your business model.

This topic includes the following information:

- *Preparing Trip Report Templates*
- *Preparing Trip Reports*

Preparing Trip Report Templates

A clinical administrator prepares a set of trip report templates for the CRAs (clinical research associates) to use when preparing for and writing up their visits to clinical sites. For more information about site visits, see *Creating and Managing Site Visits*.

The clinical administrator prepares the following templates for each type of site visit the CRAs typically must perform:

- Site evaluation
- Site initiation
- Site monitoring
- Site close-out

Preparing Trip Reports

The CRA (clinical research associate) is the end user of the Siebel Clinical product. Before visiting a site, the CRA uses the trip report to prepare for the visit. The follow-up items list reminds the CRA of the open activities from previous visits that the CRA can close.

After preparing a draft trip report, the CRA makes a hard copy of the report and takes this copy on the site visit. He can use the report as a reference to help keep track of the activities he completes while at the site.

After returning from a site visit, the CRA completes the trip report and generates a final report. He then submits this report to the study manager for approval. The manager reviews the report and approves it if it is satisfactory. If the manager approves the trip report, then it is then locked to prevent the CRA from making any further changes. If the trip report is not satisfactory, then the manager can reject the report and return it to the CRA for further attention.

Creating Questions for Clinical Trip Reports Using Siebel SmartScript

You can use Siebel SmartScript to create questionnaires for clinical trip reports. For information about how to create questions using SmartScript, see *Siebel SmartScript Administration Guide* .

To add comments against questions in SmartScript, the following additional configuration is required:

- You must create each comment as an individual question. Comments are always immediately followed by the corresponding question.
- For each question that is intended to be a comment, enter the value `ForceEnableQuestion.CommentForPrevQuestion` in the Save User Parameters field when creating the question.

Some SmartScript question settings listed in *Siebel SmartScript Administration Guide* are not applicable for clinical trip reports. The following information lists the question settings that are not applicable to clinical trip reports.

Question Setting	Questionnaire Exception for Clinical Trip Reports
Answer Type	The Currency data type is not supported.
Auto Sub Parm	This setting is not applicable.
Search Spec	This setting is not applicable.
Save Business Object	This setting is not applicable because the answers to questionnaires for clinical trip reports are automatically saved as part of the clinical trip reports.
Save Bus Comp	This setting is not applicable because the answers to questionnaires for clinical trip reports are automatically saved as part of the clinical trip reports.
Save Field	This setting is not applicable because the answers to questionnaires for clinical trip reports are automatically saved as part of the clinical trip reports.
Save Currency Field	This setting is not applicable because the answers to questionnaires for clinical trip reports are automatically saved as part of the clinical trip reports.
Pick Applet	This setting is not supported.
Mvg Applet	This setting is not supported.
Detail Applet	This setting is not supported.
Save Answer Table	This setting is not applicable because the answers to questionnaires for clinical trip reports are automatically saved as part of the clinical trip reports.

Question Setting	Questionnaire Exception for Clinical Trip Reports
Currency	This setting is not applicable.

You can assign a SmartScript questionnaire to a clinical trip report template after it is released using Siebel SmartScript. For information about how to release a script using Siebel SmartScript, see *Siebel SmartScript Administration Guide* .

Creating Clinical Trip Report Templates

Typically, the clinical administrator prepares a number of generic trip report templates, perhaps one designed for each of the different stages in the study. This topic describes how to create a clinical trip report. You can define additional activities, such as follow-up tasks to complete after the visit to the clinical site, in the Trip Report Template Details view.

To create a clinical trip report template

1. Navigate to the Administration - Clinical screen, then the Trip Report Templates view.
2. Create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Name	Type the name of the clinical trip report template.
Visit Type	Select the type of site visit, for example, Site Evaluation, Site Initiation, or Site Monitoring.
Protocol #	Select the protocol for the clinical site.
Region	Select the region for the clinical site.
SmartScript	Select a SmartScript questionnaire for the trip report template. The questionnaire is copied to the Questions view of the trip report when you apply the trip report template to the trip report. The questionnaire uses branching logic to dynamically determine the flow of questions by using answers to prior questions. The Siebel Clinical Trial Management System administrator determines the question hierarchy by using Siebel SmartScript. For more information about Siebel SmartScript, see *Siebel SmartScript Administration Guide* .

3. Drill down on the Name field of the trip report template to display the Trip Report Template Details view.
4. Create new records to define each trip report activity.

Field	Comments
Activity	Select the type of trip report activity. The following values are available: o Checklist o Follow-Up o Issues
Priority	Select the priority of the trip report activity.

Applying Clinical Trip Report Templates

The Template field of the Site Visits view displays all of the trip report templates that are applicable to protocol, region, and visit type details for that site visit. When you apply a trip report template to a trip report, all of the details in the template are copied to the trip report.

Checklist and follow-up activities in the Trip Report Template Details view of the trip report template are copied to the trip report, and overwrite any existing checklist and follow-up activities in the trip report.

SmartScript questionnaires in the SmartScript field of the trip report template are applied to the trip report, and appear in the Questions view. For performance reasons, the SmartScript questionnaire does not appear in the Questions view until after the user launches the SmartScript questionnaire. For more information about SmartScript questionnaires, see *Completing Questionnaires for Clinical Trip Reports*.

To apply a clinical trip report template

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit to which you want to apply a trip report template.

   The Trip Report form for the selected site visit appears.
3. Click the select button in the Template field.

   A list of templates that correspond to the protocol, region, and visit type details for the site appears.
4. Select the name of the trip report template that you want to apply, and click OK.

   When you save the Template field, the activities in the template appear in the Checklist Activities list and Follow-Up Items list.

Completing Clinical Trip Reports

After the site visit, you record the trip report details, such as:

- The planned activities that you complete
- Additional activities that you complete
- Site personnel that you meet
- Any follow-up items that arise from the trip
- Comments on any of the previous items

Anyone can update and edit the records in the Trip Report Detail view at any time. For this reason, the end user can create a static report at the completion of the site visit, using the Siebel Report Viewer. This read-only document is ideal for archiving: as a printed document, as a file, or as an attachment to the site record in the Siebel Life Sciences database.

To complete a clinical trip report

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to complete a trip report.
   The Trip Report form for the selected site visit appears.
3. On the Trip Report form, complete or edit the fields as shown in the following table.

Field	Comments
Completed	Select the date and time that you complete the site visit. This field is populated with the system date and time when you update the Visit Status field to Done. The filter in the All Follow-Up Items list uses this date to determine the closed follow-up items to show.
Visit Status	Select the status of the site visit, for example, Planned or Completed.
Reviewer Comments	Displays the reviewer comments if a reviewer submits a trip report with status Rejected.
Approver Comments	Displays the approver comments if an approver submits a trip report with status Rejected.
Visit Type	Select the nature of the visit, for example, Pre-Study, Site Initiation, or Site Monitoring.
Attendees	Select the contacts (site personnel) that you meet during the visit.
Reviewer	Select the user who reviews the trip report. An automated email notification is sent to the reviewer when you update the status of the trip report to Submitted.

Field	Comments
Approver	Select the user who approves the trip report. An automated email notification is sent to the approver when the reviewer updates the status of the trip report to Submitted for Approval.
Assigned To	Select the users assigned to the trip report. The team member who creates the trip report is the primary owner.
Trip Report Completed	Select the date that the trip report is complete and ready for submission. This field is populated with the system date when you update the Visit Status field of the trip report to Completed.

4. Navigate to the Checklist Activities view, complete the Status and Comments fields for planned activities, and add any unplanned activities that you completed.
5. Navigate to the Follow-Up Items view, and complete the following steps:
    a. Add any follow-up activities resulting from the site visit.
    b. In the Current Trip Follow-Up Items list, click Menu (the cogwheel icon), and choose Select All to display all open follow-up items and those items closed between the current and previous trip.
    c. Update the records for those follow-up items that you addressed during the site visit.

    Some fields are described in the following table.

Field	Comments
Status	Displays a value of Done when you select a completed date for the item.
Completed Date	Select the resolution date and time of the follow-up issue. You must populate this field because the filter in the All Follow-Up Items list uses this date to determine the closed follow-up items to show.

6. Set the Trip Report Status field to Submitted.

    The report is submitted to the reviewer for review.

Completing Questionnaires for Clinical Trip Reports

This topic describes how to complete a questionnaire for a clinical trip report. You launch the questionnaire in the SmartScript player from the Questions view of the trip report. Questions and responses along with comments (if any) are saved in the Questions list.

To complete a questionnaire for a clinical trip report

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for the required trip report.

   The Trip Report form for the selected site visit appears.
3. Navigate to the Questions view.
4. Click Answer to launch the questionnaire for the trip report in the SmartScript player.
5. Complete the questionnaire by adding responses and comments (if any).
6. Click Finish or Finish Later.

   The responses and comments are saved with the questions in the Questions list. You can filter questions as follows:

   - To display only answered questions, select Show Answered.
   - To display all questions in the questionnaire for the trip report, select Show All.

Deleting Unanswered Questions from Questionnaires of Clinical Trip Reports

This topic describes how to delete unanswered questions from a questionnaire for a clinical trip report, using the LS Clinical Questions Batch Clean-up repository workflow process.

Note: This task requires administrator privileges.

To delete unanswered questions from a questionnaire of a clinical trip report

1. Navigate to the Administration - Server Management screen, then the Jobs view.
2. Create a new record and complete the necessary fields.
3. Set the Component/Job field to Workflow Process Manager.
4. In the Job Parameters list, create a new record and complete the necessary fields.
5. Set the Name field to Workflow Process Name and the Value field to LS Clinical Questions Batch Clean-up.
6. Select the record in the Jobs list, and click Submit Job.
7. Refresh the screen and verify that the State field updates to Success.

   All unanswered questions in the questionnaire for the clinical trip report are now deleted.

Tracking Case Report Forms

This topic describes how to create a CRF (case report form) tracking activity. You capture relevant information, such as review date and page numbers verified, for each CRF record.

To track case report forms

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to track case report forms.
3. Navigate to the Case Report Forms Tracking view.
4. To add case report forms for scheduled subject visits, complete the following steps:
    a. Click Add Scheduled.
    b. Select the subject visits in the dialog box that appears.
    c. Click OK.

    The case report forms for selected subject visits appear in the Case Report Forms Tracking view.
5. To add case report forms for unscheduled subject visits, complete the following steps:
    a. Click Add Unscheduled.
    b. Select the subject visits in the dialog box that appears.
    c. Click OK.

    The case report forms for selected subject visits appear in the Case Report Forms Tracking view.
6. In the case report forms, complete the necessary fields as shown in the following table.

Field	Comments
Source Verified	Select this field when you verify the CRF against the source document.
Retrieved	Select this field when you retrieve the CRFs from the site.
Page Numbers Verified	Type the CRF page numbers that you verify.
Charts Reviewed Date	Select the date and time that you review the clinical charts.
Forms Signed Date	Select the date and time that you sign the CRFs.

Automated Validation and Notification Messages for Clinical Trip Reports

The state model for the trip report provides the order of transition for values in the Trip Report Status field to indicate the progress of the trip report. The following table describes the values for the Trip Report Status field, the update type (such as automatic or user), the trip report validation, and the automated notification emails sent to the assignee's Universal Inbox for each status, where applicable.

Note: The Notifications feature is enabled by default for all Siebel Business Applications so all notification messages for clinical trip reports are sent directly to the screens of users. Messages appear in notification panes that users access by clicking Notification on the application banner. For more information about using, administering and reviewing notifications, see *Siebel Fundamentals Guide* .

Value in Trip Report Status Field	Description	Update Type	Validation	Automated Email Notification
Not Started	The end user created the trip report, but processing is not yet started. This status is the initial default value for all trip reports.	System	Not applicable.	Not applicable.
In Progress	The end user started to work on the trip report, and it is not yet complete.	System, if the trip report is created using a template. User, if the trip report is not created using a template.	Not applicable.	Not applicable.
Completed	The end user completed the trip report, and it is ready for the end user to submit for review.	User	The trip report is validated to ensure that the Completed Date is populated. The Completed Date is a prerequisite for selecting Completed.	Not applicable.
Submitted	The end user submitted the trip report to the reviewer for review.	User	The trip report is validated to ensure that a reviewer is assigned.	The following automated email is sent to the reviewer: Review Trip Report [Trip Report Name]. If you change the reviewer when the Trip Report Status field is Submitted, then this notification email is sent to the new reviewer.
Reviewed with Comments	The reviewer or approver added review comments requiring a modification to the trip report.	User	Not applicable.	The following automated email is sent to the trip report owner: Rectify Trip Report [Trip Report Name].
Rejected	The reviewer or approver rejected the trip report.	User	The trip report is validated to ensure that one of the	The following automated message is sent to the trip report owner:

Value in Trip Report Status Field	Description	Update Type	Validation	Automated Email Notification
			following fields is completed: • Reviewer Comments • Approver Comments	Rectify Trip Report [Trip Report Name].
Revised	The end user modified the rejected trip report, and it is not yet resubmitted for review.	User	Not applicable.	Not applicable.
Submitted for Approval	The reviewer submitted the trip report for formal review, without comments or with comments that do not require a change to the trip report.	User	The trip report is validated to ensure that an approver is assigned.	The following automated email is sent to the approver: Approve Trip Report [Trip Report Name]. If the you change the approver when the Trip Report Status field is Submitted for Approval, then this notification email is sent to the new approver.
Approved	The approver approved the trip report, and it is now read-only. When the approver clicks the Approved button, the Trip Report Status field is updated to Approved.	System	Not applicable.	Not applicable.

Tracking Completion Status for Clinical Trip Reports

This task describes how to track the real-time progress for a trip report in the Summary view. You track the status for the following fields in the clinical trip report:

- Checklists Completed
- Questions Answered
- Current Follow-Ups Completed
- All Follow-Ups Completed
- CRF Tracking Completed
- Total Attendees

To track the completion status for a clinical trip report

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to track the status of the trip report.

   The Trip Report form for the selected site visit appears.
3. Navigate to the Summary view and review the summary status.

   Some fields are described in the following table.

Field	Comments
Checklists Completed	Displays the number of completed checklists and the total number of checklists. The drill-down navigates to the Checklist Activities view. All checklists in the Checklist Activities view that have a Status of Done or Completed are listed as completed in the Summary view.
Questions Answered	Displays the number of answered questions, the total number of SmartScript questions for the trip report, and the SmartScript questionnaire status. The value ranges are as follows: ○ **0 of 0, Not Assigned.** The user has not assigned a SmartScript questionnaire to the trip report. ○ **[Total Answered] of [Total Questions], In Progress.** The user launched the SmartScript questionnaire, and it is in progress. ○ **[Total Answered] of [Total Questions], Finished.** The user completed answering all of the questions. The drill-down navigates to the Questions view.
Current Follow-Ups Completed	Displays the number of completed follow-up activities and the total number of follow-up activities for the current trip report. The drill-down navigates to the Current Trip Follow-Up Items view. All follow-ups in the Current Trip Follow-Up Items view with a value in the Completed Date field are listed as completed in the Summary view.
All Follow-Ups Completed	Displays the number of completed follow-up activities and the total number of follow-up activities for all trip reports applicable to the clinical site. The drill-down navigates to the All Follow-Up Items view. All follow-ups in the All Follow-Up Items view with a value in the Completed Date field are listed as completed in the Summary view.
CRF Tracking Completed	Displays the number of completed CRF (case report form) tracking activities and the total number of CRF tracking activities. The drill-down navigates to the CRF Tracking view. All CRF tracking activities in the CRF Tracking view that have a status of Source Verified are listed as completed in the Summary view.
Total Attendees	Displays the total number of attendees assigned to the trip report.

Tracking Status Accruals for Clinical Subjects of Sites

This task describes how to track the progress of subject status accruals for a clinical site by creating a real-time snapshot of the current subject status accruals for the site. The CRA (clinical research associate) can use the snapshot to verify the subject status data that an end user manually records during a site visit.

To track status accruals for clinical subjects of a site

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to track the status accruals for subjects.

   The Trip Report form for the selected site visit appears.
3. Navigate to the Summary view.
4. Click Capture in the Subject Status Snapshot applet to generate a real-time snapshot of the status accruals for clinical subjects.

   Some fields are described in the following table.

Field	Comments
Visit Type	Displays the type of clinical visit. The following clinical visit types are preconfigured: o Screening o Rescreening o Enrollment o End of Study
Subject Status	Displays the subject status. The following subject visit statuses are preconfigured: o Screened o Screen Failure o Randomized o Enrolled o Completed o Early Terminated o Re-screened o Withdrawn
Total Accrual Number	Displays the number of current and past subject status accruals that are automatically created for the site visit.

Field	Comments
Total Actual Number	Type the number of current and past subject status accruals that you manually recorded during the site visit.
Current Accrual Number	Displays the number of current subject status accruals that are automatically created for the site visit.
Current Actual Number	Type the number of current subject status accruals the you manually recorded during the site visit.
Comments	Type a description of any discrepancy between accrual numbers and actual numbers.
Reviewer Comments	Type reviewer comments about the trip report. Only the assigned reviewer can modify this field.
Time Stamp	Displays the date and time that the snapshot is generated.

Viewing Universal Inbox Notifications for Action Items of Clinical Trip Reports

The Inbox provides a centralized list of items requiring your attention, such as clinical trip reports requiring review, revision, and approval. The following procedure shows you how to access and view Universal Inbox notifications for action items of clinical trip reports. Alternatively, you can click Notification on the application banner to access and view all notification messages, including those for clinical trip reports.

Note: The Notifications feature is enabled by default for all Siebel Business Applications so all notification messages for clinical trip reports are sent directly to the screens of users. Messages appear in notification panes that users access by clicking Notification on the application banner. For more information about using, administering and reviewing notifications, see *Siebel Fundamentals Guide* .

To view Universal Inbox notifications for action items of a clinical trip report

1. From the application-level menu, choose Navigate, then Site Map.
2. Click Inbox.

   The views available for the inbox appear.
3. Click Inbox Items List.

The list of notifications for your trip reports appears. The action required for each trip report appears in the Name field.

4. Drill down on the Name field to view each trip report requiring action.

Reviewing Clinical Trip Reports

The user designated in the Reviewer field of the Trip Report form can review trip reports with a status of Submitted. An automated notification email is sent to the reviewer when an end user updates the trip report status to Submitted.

Access control applies to the Reviewer Comments field. Only the user designated in the Reviewer field of the Trip Report form can edit the Reviewer Comments field.

To review a clinical trip report

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, select My Team's Site Visits in the visibility filter.

   All site visits for your team appear.
3. Query the list for site visits with a Visit Status field value of Submitted or Submitted for Approval.
4. For the required report, drill down on the Visit Start field.

   The Trip Report form appears.
5. Review the report.
6. Set the Trip Report Status field to one of the following values:

   - **Reviewed with Comments.** Use this value if minor changes to the trip report are required. Enter the required corrections in the Reviewer Comments field.
   - **Rejected.** Use this value if major changes to the trip report are required. Enter the required corrections in the Reviewer Comments field.
   - **Submitted for Approval.** Use this value if the trip report does not require additional changes, and is ready for approver review.
   - **Obsolete.** Use this value to retire the current or active version of a trip report. This makes it possible to reopen and create a new version of the trip report.

   The date and time of the review of the clinical trip report are recorded in the Reviewed Date field.

Approving Clinical Trip Reports

The assigned approver can approve trip reports with a status of Submitted for Approval. Only the user designated in the Approver field of the trip report has approval permission. An automated notification email is sent to the approver when an end user updates the trip report status to Submitted for Approval. If the approver sets the Trip Report Status field to Rejected, then the CRA (clinical research associate) has the opportunity to revise the report and then resubmit it for approval.

Note: The User Authentication applet for approver verification of a trip report is not enabled by default. To enable this functionality, your system administrator must set the Enable Verification option to Y in the Named Method 2 user property in Siebel Tools. For more information about this user property, see *User Properties for Business Components in Siebel Clinical*.

Access control applies to the Approver Comments field. Only the user designated in the Approver field of the Trip Report form can edit the Approver Comments field.

To approve a clinical trip report

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, select My Team's Site Visits in the visibility filter.

   All site visits for your team appear.
3. Query the list for site visits with a Visit Status field value of Submitted or Submitted for Approval.
4. For the required report, drill down on the Visit Start field.

   The Trip Report form appears.
5. Review the report.
6. (Optional) Add approval comments in the Approver Comments field.
7. Click Approve.

   The User Authentication view appears.
8. Enter user credentials, and click Verify.

   The Trip Report Status field is updated to Approved, the approval date and time are recorded in the Approved Date field, and the site visit record and trip report become read-only.

Making Clinical Trip Reports Obsolete

Active trip reports can be made obsolete at any time.

To make a clinical trip report obsolete

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, select My Team's Site Visits in the visibility filter.

   All site visits for your team appear.
3. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit that you want to make obsolete.

   The Trip Report form appears.
4. Set the value in the Trip Report Status field to Obsolete.

   The current version of the trip report is retired and the Version button on the trip report is activated. This makes it possible to reopen and create a new version of the trip report.

Creating New Versions of Clinical Trip Reports

After a trip report is approved or made obsolete, it is locked (becomes read-only) and the Version button on the trip report is activated. This allows you to reopen and create a new version of the trip report. You can modify and route the new version of the trip through the approvals process again.

You cannot create new versions of trip reports that are active. A message similar to the following appears if you try to create a new version from an active trip report:

Another version of this trip report exists. Use the other trip report version, or change the status of that version to Obsolete and create a new version.

To create a new version of a clinical trip report

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, select My Team's Site Visits in the visibility filter.

   All site visits for your team appear.
3. Query the list for site visits with a Visit Status field value of Approved or Obsolete.
4. For the required report, drill down on the Visit Start field.

   The Trip Report form appears.
5. Review the report.
6. (Optional) Add reviewer comments in the Reviewer Comments field.
7. Click Version.

   A new version of the trip report is created where all data from the original trip report is copied over to the newly created trip report. Note the following:
   - The value in the Version field for the new trip report changes by incrementing by one.
   - The value in the Trip Report Status field for the new trip report changes to In Progress.
   - The value in the Trip Report Status field for the original trip report (for approved trip reports only) changes from Approved to Obsolete.
8. Modify and approve the trip report as required.

   For mor e information, see *Completing Clinical Trip Reports* and *Approving Clinical Trip Reports*.

Viewing Version Information for Clinical Trip Reports

The Versions view shows all the prior trip report versions for a selected trip report.

To view version information for clinical trip reports

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to view trip report versions.

The Trip Report form appears.

3. Navigate to the Versions view.

Some fields are described in the following table.

Field	Comments
Version	The version number of the trip report.
Visit Start	The visit start date and time.
Trip Report Status	The status of the trip report, which can be Approved or Obsolete.

Viewing Geographical Location Details for Clinical Trip Reports

A third-party application records dates, times, and geographical location details for sites in the trip report for each site monitor visit to each clinical site.

Multiple site monitors can create multiple site visit records in the trip report for the same site visit. Each site monitor can create multiple site visit records in the trip report for different times on the same site visit.

To view geographical location details for a clinical trip report

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to view geographical location details.

The Trip Report form for the selected site visit appears.

3. Navigate to the Geo Location Details view.

Some fields are described in the following table.

Field	Comments
User Id	Displays the user ID of the site monitor who logs the geographical location details in the third-party clinical application.
Latitude	Displays the latitude coordinate of the site. Latitude coordinates are represented in decimal degree format. The range of acceptable values is 0 to plus or minus 90. Northern hemisphere latitudes are represented by a positive number. The number is preceded by a minus sign to represent southern hemisphere latitudes.

Field	Comments
Longitude	Displays the longitude coordinate of the site. Longitude coordinates are represented in decimal degree format. The range of acceptable values is 0 to plus or minus 180. Eastern hemisphere latitudes are represented by a positive number. The number is preceded by a minus sign to represent western hemisphere longitudes.
Date	Displays the date and time the site monitor logs the geographical location details in the third-party clinical application.
Comments	Type any comments relating to the site visit. The site monitor populates this field.

Using Audit Trail for Reviews and Approvals of Clinical Trip Reports

The Approvals view provides a summary audit trail of the changes to the trip report status, including the dates and times of review and approval operations, and the details applicable to the users who complete those operations.

To use audit trail for reviews and approvals of a clinical trip report

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for the required trip report.

   The Trip Report form for the selected site visit appears.
3. Navigate to the Approvals view.

   Some fields are described in the following table.

Field	Comments
Login	Displays the login credentials of the user who modified the field.
Status	Displays the value in the Trip Report Status field after the change occurred.
Old Status	Displays the value in the Trip Report Status field before the change occurred.
Updated	Displays the date and time that the field was modified.

Using Audit Trail for Changes to Clinical Trip Reports

The Audit Trail view provides a detailed history of the changes to trip report records. The audit trail records for the trip report show operations for the following fields:

- Comments
- Reviewer
- Reviewer Comments
- Approver
- Approver Comments
- Trip Report Status

To use audit trail for changes to a clinical trip report

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for the required trip report.
   The Trip Report form for the selected site visit appears.
3. Navigate to the Audit Trail view.
   Some fields are described in the following table.

Field	Comments
Employee Login	Displays the username of the user who changed the record.
Business Component	Displays the business component for the record where the database change occurred.
Field	Displays the name of the field where the change occurred.
Operation	Displays the type of operation that was performed, for example, New Record, or Modify.
Old Value	Displays the value in the field before the database change occurred.
New Value	Displays the value in the field after the database change occurred.
Date	Displays the timestamp of the change.
Record ID	Displays the unique identifier of the record that was changed.
Base Table	Displays the name of the primary database table where the database change occurred.

Field	Comments
Column	Displays the name of the column in which the change occurred.
Group ID	Displays the unique identifier of the group to which the user who changed the record belongs.
Table	Displays the name of table to which the selected field belongs in the Siebel database.
Row ID	Displays the unique identifier of the row in which the change occurred.

Generating Oracle BI Publisher Reports for Site Visits

You can integrate Siebel Clinical with Oracle Business Intelligence Publisher (BI Publisher) to generate reports. You can generate, view, and schedule preconfigured Oracle BI Publisher reports in Siebel Clinical. For more information about using Siebel Reports and integrating with Oracle BI Publisher, see *Siebel Reports Guide* .

The following preconfigured reports apply to site visits:

- Clinical Trip Report With CRF
- Clinical Trip Report Without CRF

To generate an Oracle BI Publisher report for a site visit

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to generate an Oracle BI Publisher report.
3. On the application toolbar, click Reports.
4. In the Run Report pane, complete the necessary fields as shown in the following table.

Field	Comments
Report Name	Select the Clinical Trip Report With CRF report or the Clinical Trip Report Without CRF report.
Output Type	Select the output type for the report.

5. Click Submit.

   The report runs.

6. Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

   A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals Guide* .

10 Managing Clinical Projects

Managing Clinical Projects

This chapter describes how to manage clinical projects. It includes the following topics:

About Managing Clinical Projects

This chapter supplements other information about project management. For information about project management, see *Siebel Project and Resource Management Administration Guide* .

Projects in Siebel Clinical help project managers manage projects for clinical trials, and are associated with individual protocols. From the Projects screen, you can enter, view, and update timelines, milestones, costs, and resources.

Scenario for Managing Clinical Projects

This topic gives one example of how to manage clinical projects. You might manage clinical projects differently, depending on your business model.

This topic includes the following information:

Setting Up and Staffing the Project

A product manager works for a large CRO (clinical research organization) that has a contract to carry out a clinical trial for a pharmaceutical company. He is responsible for setting up and running the project for a clinical trial.

First, the product manager enters some basic information about the project into Siebel Clinical, and determines the employees that can access the project data by entering them in the project access list.

To optimize the resource assignment, the product manager enters the resource requirements in the team workbook, and then uses Siebel Assignment Manager to help with the staffing. He specifies the roles, skills, competencies, and availability required for the team, and lets Resource Manager find the best candidate for the roles.

For this large project, the CRO might need some subcontractors to complete certain aspects of the project. Because the subcontractors are paid at an hourly rate, the product manager associates the appropriate billing rate list with the project. He also must add employees of the subcontracting company to the subcontractor resource list.

The product manager can add other external contacts and accounts to the project. For example, he can add information about the central laboratory and the primary contact at this laboratory.

Managing Tasks, Activities, and Risks

You can set milestones as tasks or activities. The product manager can create milestones within projects in Siebel Clinical. Each Siebel activity has a budget, and end users update the actual costs of these activities as the project progresses. Periodically, the product manager reviews these project costs, making sure that the project stays within budget. Payments you make to sites for subject activities are rolled up to the project costs.

You document project risks as they arise, and you document the resolution activities to address the risks.

Process of Managing Clinical Projects

This topic details sample tasks that administrators and end users often perform when managing clinical projects. Your company might follow a different process according to its business requirements.

Perform the administrative tasks described in this topic before performing the related end-user tasks.

Administrator Tasks

The tasks that an administrator must complete to support projects depends on the project features that the organization uses. You might not have to perform all the tasks listed in this topic. These tasks must occur before the project manager creates the project.

The following list shows the tasks administrators typically perform to manage clinical projects:

- *Creating Activity Templates for Clinical Projects*. Many project managers use these templates to carry out similar clinical trials.
- *Setting Up Employee Profiles for Clinical Projects*. Maintain the employee profiles of skills and competencies that Siebel Assignment Manager uses.

- *Setting Up Position Types and Rate Lists for Billing*. The position types and rate lists are required to allow subcontractors (and employees) to bill the project for their time.

End-User Procedures

The following list shows the tasks end users typically perform to manage clinical projects:

- *Creating Clinical Projects*. You associate protocols with projects.
- *Associating People and Accounts with Clinical Projects*. Give employees access to the project; add contacts and accounts to the project team workbook.
- *Creating Activities and Tasks for Clinical Projects*. Standalone activities are not associated with tasks.
- *Monitoring Costs for Clinical Projects*. View costs for clinical projects.
- *Managing Risk for Clinical Projects*. Document project risks and resolution activities.

Creating Activity Templates for Clinical Projects

You can create activities in the Projects screen. If the study managers primarily enter activities in the Projects screen, then creating activity templates for projects is advantageous.

To create an activity template for projects, you create an activity template with a Project type. The Protocol Type field is optional because you can apply the activity template to any project, regardless of the protocol associated with the project. In the Activity Template Details list, create records to describe activities and milestones for the project. For information about how to create activity templates, see *Siebel Applications Administration Guide* .

This task is a step in *Process of Managing Clinical Projects*.

Setting Up Employee Profiles for Clinical Projects

End users can use Siebel Assignment Manager to automatically search the employee database for the available employees whose skills best fit the needs of the project. Siebel Assignment Manager requires that you set up profiles of skills and competencies for employees. For information about using Siebel Assignment Manager, see *Siebel Assignment Manager Administration Guide* .

Use of Siebel Assignment Manager is not required. End users can assign team members directly into the Team Workbook view, without using Siebel Assignment Manager.

This task is a step in *Process of Managing Clinical Projects*.

Setting Up Position Types and Rate Lists for Billing

If project team members bill their time to the project through the Team Workbook view, then set position types and rate lists.

You set up position types, such as Consultant, as products, and you designate them as resources. You then set up lists of hourly rates for the position types. When you apply the rate list to the project, the hourly rates for the team members are automatically supplied in the team workbook. For more information about position types and rate lists for professional services, see *Siebel Applications Administration Guide* .

This task is a step in *Process of Managing Clinical Projects*.

Creating Position Types as Products

Complete the procedure in this topic to create position types as products.

To create position types as products

1. Navigate to the Administration - Product screen, then the Products view.
2. In the Products list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Product	Type the product (resource) name, for example, Consultant.
Project Resource	Select this field to indicate that the product is a project resource.

Creating Rate Lists

Complete the procedure in this topic to create a rate list.

To create a rate list

1. Navigate to the Administration - Pricing screen, then the Rate List view.
2. In the Rate Lists list, create a new record and complete the necessary fields.
3. In the Rate Lists list, drill down on the Rate List field.
4. In the Rate List Line Items list, create a new record.
5. In the Add Position Types dialog box, select the Position Type and click OK.

   This list of resources is created as a product.
6. In the Rate List Line Items list, complete the remaining fields.

Creating Clinical Projects

You can create a project record and associate a protocol with the project.

Note: It is recommended that you associate a protocol with only one project. However, you are not prevented from associating a protocol with multiple projects. In this case, costs associated with payments to sites are rolled up to each project.

This task is a step in *Process of Managing Clinical Projects*.

To create a clinical project

1. Navigate to the Projects screen, then the List view.
2. In the Project list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Project ID	Type a unique identification number for the project.
Account	Select the account for the project. For example, select the name of the pharmaceutical company for which you carry out the project.
Start	Select the start date and time for the project.
End	Select the end date and time for the project.
Protocol #	Select the protocol for the project. All available protocols are available for selection from the Pick Protocol dialog box. The project creator does not have to be a member of the protocol team.
Actual Cost	Displays the actual cost of the project. This field is calculated by summing the actual costs of all the tasks, activities, and site payments associated with the project.
Revenue	Type the total revenue for the project. Click the currency calculator button for this field to enter the amount of revenue, the currency, and the exchange date for the currency.
Budgeted Cost	Displays the budgeted cost of the project. This field is calculated by summing the budgeted costs of all the tasks, activities, and site payments associated with the project.

3. Drill down on the Name field of the project, and navigate to the More Info view to add more information.

   Some field are described in the following table.

Field	Comments
Rate List	Select the rate list for the project if a rate list is set up for the project team members. Click the show more button if this field is not visible. For more information, see *Setting Up Position Types and Rate Lists for Billing*.
Description	Type a description of the project.

Associating People and Accounts with Clinical Projects

You can give employees in Siebel Clinical access to the project and add them to the team workbook.

You can associate contacts with projects through the Contacts view and the Organizational Analysis view. The same contacts appear in the Contacts view and the Organizational Analysis view.

You can associate accounts with projects through the Partners view and the Subcontractors view. Adding accounts to the Subcontractors view allows you to add employees from the subcontracting accounts to the project team workbook. For more information about adding subcontractors, see *Siebel Project and Resource Management Administration Guide* .

This task is a step in *Process of Managing Clinical Projects*.

Adding Employees to Projects

Complete the procedure in this topic to add employees to a project.

To add employees to a project

1. Give employees access to a project by adding them to the Access view.
2. For more information about providing access to a project, see *Siebel Project and Resource Management Administration Guide* .
3. Allow end users to assign employees and subcontractors to activities, and allow employees and subcontractors to bill time to the project by adding them to the Team Workbook view.
4. If a rate list is set up, then make sure that the Resource field on the Resource Detail form of the Team Workbook view is set for the team members. For more information about the team workbook for project management, see *Siebel Project and Resource Management Administration Guide* .

Adding Contacts to Projects

Complete the procedure in this topic to add a contact to a project using the Organization Analysis view.

To add a contact to a project

1. Navigate to the Projects screen, then the List view.
2. In the Project list, drill down on the Name field of the project.

3. Navigate to the Organization Analysis view.
4. From the Organization Analysis drop-down list, select Contacts.
5. In the Contacts list, create a new record and complete the necessary fields.
6. From the Contacts drop-down list, select Organization Analysis.
7. An organization chart of the contacts appears. Any employee-manager relationships set in Step 5 are indicated.

Adding Partner Accounts to Projects

Complete the procedure in this topic to add a partner account to a project.

To add a partner account to a project

1. Navigate to the Projects screen, then the List view.
2. In the Project list, drill down on the Name field of the project.
3. Navigate to the Partners view.
4. In the Partners list, create a new record and complete the necessary fields.
5. The Site field is a unique identifier for the site of the account. This field is not related to the sites where you carry out clinical trials.

Creating Activities and Tasks for Clinical Projects

You can create activities for the project in the following ways:

- Enter activities in the Activities view.
- Generate activities in the Activity Plans view by applying an activity template to projects.
- Manually enter activities in the Activity Plans view. These activities must be associated with an activity plan that is based on a template.
- Create a task in the Task view and associate activities with the task.

A task is a container for activities. Activities associated with tasks are different from regular *standalone* activities. Activity templates for projects cannot generate activities that belong to tasks. You can only manually create these activities from within the Project Task Activity view. You cannot add a standalone activity to a task, nor can you disassociate an activity for a task from the task. For more information about creating activities and tasks for project management, see *Siebel Project and Resource Management Administration Guide* .

This task is a step in *Process of Managing Clinical Projects*.

Creating Activities for Projects

Complete the procedure in this topic to create an activity for a project using an activity template.

Note: You can also manually create activities in the Activities view.

To create an activity for a project

1. Navigate to the Projects screen, then the List view.

2. In the Project list, drill down on the Name field of the project.
3. Navigate to the Activity Plans view.
4. In the Activity Plans list, create a new record.
5. In the Template field, select a template from the drop-down list.

   The activities associated with the activity plan appear in the Activities list.

Creating Tasks and Associated Activities

Complete the procedure in this topic to create a task and associated activities.

To create a task and associated activities

1. Navigate to the Projects screen, then the List view.
2. In the Project list, drill down on the Name field of the project.
3. Navigate to the Tasks view.
4. In the Tasks list, create a new record and complete the necessary fields.
5. In the Tasks list, drill down on the Name field.
6. In the Activities list, create a new record and complete the necessary fields.

Monitoring Costs for Clinical Projects

The Cost view provides you with a valuable summary of all costs associated with a particular project and protocol.

The cost items appear in the following lists:

- **Project Activities.** Displays those records from the Activities view where the Cost field is selected.
- **Project Tasks.** Displays those records from the Tasks view where the Cost field for the *task* is selected. The actual cost and budgeted cost for a task are determined by summing the costs of the activities contained in the task.
- **Clinical Payments.** Displays payments made to the sites associated with the protocol. These payment amounts are rolled up into the Actual Cost field in the project record.

End users cannot create, modify, or delete records in the Costs view.

Note: All costs in this view are in the default currency set for the project.

This task is a step in *Process of Managing Clinical Projects*.

To monitor costs for clinical projects

1. Navigate to the Projects screen, then the List view.
2. In the Project list, drill down on the Name field of the project.
3. Navigate to the Costs view.
4. Click a hyperlink in the Clinical Payments or Project Tasks list to see the activities associated with a cost item.

Managing Risk for Clinical Projects

An important aspect of project management is risk management. The features of the Risks view allow you to enter information about project risks and create and assign resolution activities to address the risks. For more information about assessing risks for project management, see *Siebel Project and Resource Management Administration Guide* .

This task is a step in *Process of Managing Clinical Projects*.

To manage risk for clinical projects

1. Navigate to the Projects screen, then the List view.
2. In the Project list, drill down on the Name field of the project.
3. Navigate to the Risks view.
4. In the Risks list, create a new record and complete the necessary fields.
5. In the Risks list, drill down on the Name field.
6. In the Resolution Activities list, create a new record and complete the necessary fields.

About Views in the Projects Screen

Many views are available in the Projects screen of the Siebel Clinical. You can choose to use only some of these views. The following table describes the views that are available in the Projects screen.

View	Comments
Access	Use this view to provide project access. Add the names of the project team members and also managers or executives who want access to monitor the progress of the project. The Access view has a similar function to the Team field in other screens.
Activities	Use this view to manage activities associated with the project. You might manually create activities in this view, or activity templates for projects might create these activities. Activities belonging to tasks do not appear in this view.
Activity Plans	Use this view to generate activities from activity templates for projects. You can manually add more activities to the activities already associated with an activity plan.
Attachments	Use this view to attach project documents. For general information about attachments, see *Siebel Fundamentals* .
Calendar	Use this view to manage a monthly calendar of the activities associated with the project. Activities belonging to tasks and standalone activities appear in this view. For general information about the calendar views, see *Siebel Fundamentals* .
Contacts	Use this view to maintain a list of contacts associated with the project. Enter names of employees in subcontracting or partner organizations.

View	Comments
Financial Profile	Use this view to gain an overall perspective of a project's financial information, status, and progress. You can change the Delivery status for the project. For more information, see *Siebel Project and Resource Management Administration Guide* .
Invoices	Use this view to create invoices for time and expenses that apply to a project. For more information, see *Siebel Project and Resource Management Administration Guide* .
Notes	Use this view to keep private and public notes about the project. For general information, see *Siebel Fundamentals* .
Orders	Use this view to create a product or material order and associate it with the project. For more information, see *Siebel Project and Resource Management Administration Guide* .
Organizational Analysis	Use this view to see an organizational chart of contacts that shows the relationships between them.
Partners	Use this view to maintain a list of partner accounts associated with the project. You can keep a list of accounts associated with the project, such as vendors who handle printing of the clinical trial materials or shipping of sample drugs. Because the views for Partners, Subcontractors, and Clinical Contacts contain account information, you can use one or more of these views to keep track of accounts associated with a project.
Risks	Use this view to maintain a list of the risks associated with the project and resolution activities required to address those risks.
Status Report	Use this view to create a status report summarizing the project's progress, forecast, and issues. For more information, see *Siebel Project and Resource Management Administration Guide* .
Subcontractors	Use this view to keep a list of subcontractors associated with the project. For more information, see the description of the Partners field.
Tasks	Use this view to create and modify tasks for the project.
Team Workbook	Use this view to assign team members to roles in the project. You can manually assign team members, or Siebel Assignment Manager can automatically assign them. Team members must be listed in the workbook before you can assign them to activities.
Time & Expense	Use this view to adjust and summarize time sheets and expense reports associated with the project. For more information about time sheets and expense reporting, see *Siebel Project and Resource Management Administration Guide* .

11 Managing Clinical Training

Managing Clinical Training

This chapter covers how to manage clinical training. It includes the following topics:

About Managing Clinical Training

Clinical Trials involve personnel at multiple sites. Companies and CROs (clinical research organizations) that conduct clinical trials must train and certify these people about those trials. This education is an important aspect of risk based monitoring and helps companies and CROs to reduce monitoring costs and expedite the clinical trail process. Companies and CROs are responsible for making sure that site personnel understand:

- The ethical aspects of research involving human subjects.
- The rules and regulations of regulatory agencies.
- Their roles and responsibilities in clinical trials.
- The appropriate SOPs (standard operating procedures) and work instructions for clinical trials.
- The various aspects of clinical trials, such as their clinical indications.

As part of the planning for clinical trials, administrators create training plans to manage the training of personnel. These training plans include training topics. Users can then track these training topics for themselves and close the topics when they complete them. This tracking provides an audit record of the training for regulatory agencies.

Setting Up Training Topics for Clinical Training

Administrators set up training topics for clinical training so that they can associate the topics with versions of training plans. For more information about associating topics with versions of training plans, see *Creating Versions of Training Plans*.

Administrators can associate a single topic with multiple training plans. Also, users can manually add to sites the training topics that administrators create. For more information, see *Changing Training Topics for Clinical Sites*.

After you publish a version of a training plan with associated topics, you cannot change the field values (except for the value in the Obsolete Date field) for those topics in the Training Topics view of the Administration - Clinical screen. If you change the field values for a topic in the Training Topics view of the Administration - Clinical screen after you associate the topic with an unpublished version of a training plan, then the changed values are reflected in the topic for that version of the training plan.

To set up a training topic for clinical training

1. Navigate to the Administration - Clinical screen, then the Training Topics view.
2. In the Training Topics list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Name	Type the name of the training topic.
Category	Select the type of training applicable to the training topic.
Role	Select the roles of the users who must complete the training topic. To select a role, click the select button in the field to open the Contact Roles dialog box, click New (the plus (+) icon) to select the Role field in the dialog box, and then select a value from the drop-down list for the Role field. Click OK after you select all of the appropriate roles for the training topic. If you do not select any roles, then all contacts for the clinical sites that are associated with the topic must complete the topic.
Description	Type a description of the training topic.
Mandatory	Select this field to indicate that completing the training topic is mandatory.
Duration	Type an estimate of the numeric value for the time that is needed to complete the training topic.

Field	Comments
Duration Unit	Select the units of time that apply to the numeric value that you enter in the Duration field.
Created Date	Displays the date and time that you create the training topic.
Obsolete Date	Select the date and time that the training topic is inactive. If you populate this field for a topic after publication of a training plan that contains this topic, then the topic is deleted from the site to which it is published. Before you can delete a topic, you must populate this field for the topic and then save the topic record. You can delete only the topics that are not yet associated with published plans. If you want to indicate that the training topic is again active, then clear this field. You cannot add an obsolete training topic to a training plan. If you add a training topic to a training plan before the topic is obsolete, then the topic remains on the training plan.

Creating Training Plans

Administrators create training plans and then designate the criteria for those plans and the training topics for versions of those plans. For more information about designating the criteria, see *Adding Criteria to Training Plans*. For more information about designating the training topics for versions, see *Creating Versions of Training Plans*.

When administrators publish the plans, the training topics in those plans are automatically associated with the appropriate contacts for the appropriate sites. The Role field value for the training topics in the plans determines the appropriate contacts. The plan criteria determines the appropriate sites.

To create a training plan

1. Navigate to the Administration - Clinical screen, then the Training Plans view.
2. In the Training Plans list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Name	Type the name of the training plan.
Description	Type a description of the training plan.
Version Number	Displays the number for the version of the training plan when you select a value of Approved in the Status field for that version, and then save the version record. For more information, see *Creating Versions of Training Plans*.

Field	Comments
Process Status	Displays the status of the publishing process for the training plan as follows: o When you create a new record for a training plan, this field value defaults to Not Started. o When you click the Publish button to publish the training plan, this field value changes from Not Started to Publishing. o After publishing is complete, and publishing is unsuccessful, this field value changes from Publishing to Failed. o After publishing is complete, and publishing is successful, this field value changes from Publishing to Published. o When you select a value of Approved in the Status field for a new version (but not the first version) of the training plan, and then save the version record, this field value changes from Published to Not Started.
Created Date	Displays the date and time that you create the training plan.
Obsolete Date	Select the date and time that the training plan is inactive. After you populate this field and then save the plan record, you cannot change the field values for the training plan, the criteria for the training plan, or the versions for the training plan. You cannot delete training plans. If you want to indicate that the training plan is again active, then clear this field. After the training plan is again active, you can change it.
Sites Processed/ Total Sites	Displays the number of sites that the publishing process associated with the training plan (sites processed) compared to the number of sites that apply to the training plan (total sites). This field is automatically populated when you publish the training plan. If you successfully publish the training plan, then the number of processed sites equals the number of total sites. If you fail to successfully publish the training plan, then the number of processed sites is not equal to the number of total sites. If you create a new approved version of the training plan, then this field value is cleared.
% Completed	Displays the fraction in the Sites Processed/Total Sites field as a percentage. This field is automatically populated when you publish the training plan. If you successfully publish the training plan, then this field value is 100%. If you fail to successfully publish the training plan, then this field value is less than 100%. If you create a new approved version of the training plan, then this field value is cleared.
Publish Result	Displays the final result of the process to publish the training plan. If you create a new approved version of the training plan, then this field value is cleared.

Field	Comments

Adding Criteria to Training Plans

Administrators add criteria to training plans to designate the sites to which the plans apply. When they publish the training plans, the appropriate contacts for these sites are automatically associated with the training topics in those plans. The Role field value for the training topics in the plans determines the appropriate contacts. Also, users can manually add training plans to sites. For more information, see *Adding Training Plans to Clinical Sites*.

After you publish a version of a training plan, you cannot change or delete the criteria for that training plan.

To add criteria to a training plan

1. Navigate to the Administration - Clinical screen, then the Training Plans view.
2. Drill down on the Name field of the training plan for which you want to add criteria.
3. Navigate to the Criteria view.
4. In the Training Plan Criteria list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Scope	Select the scope of the training plan as follows: o If you select a value of All, then the training plan applies to all sites in Siebel Clinical, and you cannot enter values in the other fields of the Training Plan Criteria list. You cannot create more criteria records for the training plan. o If you select a value of Specific, then the training plan applies to specific sites in Siebel Clinical, and you designate these sites in the other fields of the Training Plan Criteria list. You can create more criteria records for the training plan.
Indication	Select the clinical indication that applies to the training plan.
Trial Phase	Select the trial phase that applies to the training plan.
Site Status	Select the site status that applies to the training plan.
Protocol #	Select the protocol number that applies to the training plan. The values that you select for the indication and trial phase determine the values that are available to you for selection in this field. If you select a protocol number and subsequently select a value for an indication or a trial phase that is not associated with that protocol number, then the criteria record that you create has no effect because no protocols meet the criteria.

Field	Comments
Region	Select the region that applies to the training plan. The value that you select for the protocol number determines that values that are available to you for selection in this field.

5. If necessary, create more new records in the Training Plan Criteria list to add more criteria to the training plan.

Creating Versions of Training Plans

Administrators create versions of training plans so that they can associate training topics with those plans. As business needs change over time, they can create new versions of training plans to accommodate those needs.

After you publish a version of a training plan, you cannot change the data in that version. For example, you cannot add training topics to or delete training topics from that version. If you want to change the data in an existing training plan, then you must create a new version of the plan, and publish the plan again.

After you publish a version of a training plan, you cannot delete that version.

To create a version of a training plan

1. Navigate to the Administration - Clinical screen, then the Training Plans view.
2. Drill down on the Name field of the training plan for which you want to create a version.
3. Navigate to the Versions view.
4. In the Versions list, create a new record and complete the necessary fields as shown in the following table.

Field	Comments
Version Number	Displays an automatically generated version number. The first version record that you create is automatically populated with a version number of 1, the second version record that you create is automatically populated with a version number of 2, and so on.
Name	Type the name of the version of the training plan.
Status	Select a value of Approved in this field to indicate that this version is the approved version of the training plan. Only one version of a training plan can have an approved status. You must select the Approved value and then save the version record before you can publish the training plan. You are not allowed to select the Approved value until you add at least one training topic to the version. For more information about adding training topics to a version, see Step 5. In addition, this field displays an automatically generated value for the status of the version as follows: o When you create a new version record, this field value defaults to Draft.

Field	Comments
	○ When you click the Publish button to publish the training plan for this version record, this field value does not change from Approved. ○ When you select the Approved value in this field for another version record in the training plan, this field value changes from Approved to Archived for this version record.
Comments	Type appropriate comments about the version of the training plan.
Created Date	Displays the date and time that you create the version of the training plan.
Published Date	Displays the date and time that you publish the version of the training plan.
Archived Date	Displays the date and time that you archive the version of the training plan.

5. Complete the following steps to select the training topics for the version:

   a. In the Training Topics list, click Add Topics.
   b. In the Training Topics dialog box that appears, select the training topics for the version.

      To select multiple topics, hold down the CTRL key and click each topic record. Topics that have a value in the Obsolete Date field are not available for selection. For information about setting up the training topics that appear in this dialog box, see *Setting Up Training Topics for Clinical Training*.
   c. Click OK.

      The selected topics appear in the Training Topics list. You cannot change the field values in these selected topic records. However, you can delete the topic for which you want to change the field values, change the field values for the topic in the Training Topics view of the Administration - Clinical screen (if the topic is not associated with another published training plan), and then add the changed topic to the version again.

About Publishing Training Plans

After administrators create training plans, they publish the training plans so that the training topics in those plans are automatically associated with the appropriate contacts for the appropriate sites. The Role field value for the training topics in the plans determines the appropriate contacts. The plan criteria determines the appropriate sites.

The publishing process for a training plan is a batch job that runs in the background. Consequently, users are not prevented from using other functionality in Siebel Clinical while this batch job runs. To optimally run this batch job, administrators can set the Clinical_Training_Commit_Freq system preference. For more information about this system preference, see *System Preferences in Siebel Clinical*.

The duration of the publishing process for a training plan is determined by the following factors:

- The number of training topics in the plan
- The number of site records to associate with the training topics in the plan

- The number of contact records to associate with the training topics in the plan

When a user creates a site record after an administrator publishes a training plan that applies to that site, the topics in that plan are automatically associated with the new site. Likewise, the topics in that plan are automatically associated with the contacts for the new site if the Role field in the topics is blank or a Role field value in the topics is the same as the Role field value in the contact records. If the administrator populates the Obsolete Date field (in the Training Topics view of the Administration - Clinical screen) for some topics in a plan after the plan publication, then those topics are not automatically associated with a new site even though the topics exist in the training plan.

When a user creates a new contact record for an existing site after an administrator publishes a training plan that applies to that site, the topics in that plan are automatically associated with the new contact if the Role field in the topics is blank or a Role field value in the topics is the same as the Role field value in the new contact record. If the administrator populates the Obsolete Date field (in the Training Topics view of the Administration - Clinical screen) for some topics in a plan after the plan publication, then those topics are not automatically associated with a new contact even though the topics exist in the training plan.

Publishing Training Plans

Administrators can publish only training plans that have a version with a Status field value of Approved. Also, users can manually add to sites the training plans that administrators publish. During the process to publish a training plan, no one can change any of the data associated with that plan. For more information, see *About Publishing Training Plans*.

If the publishing process is unsuccessful, then possibly the server is not operating. For more information about unsuccessful publishing processes, contact your system administrator.

To publish a training plan

1. Navigate to the Administration - Clinical screen, then the Training Plans view.
2. Drill down on the Name field of the training plan that you want to publish.
3. If necessary, change the Status field for the version of the plan from Draft to Approved, and save the version record.
4. Click Publish.

   The publishing process is initiated, and the value in the Process Status field for the training plan changes from Not Started to Publishing.
5. Navigate back to the Administration - Clinical screen, then the Training Plans view to see the final status of the publishing process.

   After the process is complete, the Process Status field changes to Published if the process is successful or to Failed if the process is unsuccessful.

Adding Training Plans to Clinical Sites

When administrators publish training plans, the training topics in those plans are automatically associated with the clinical sites that meet the criteria in the plans. When a clinical site does not meet the criteria in a training plan, but the training plan applies to the site, you can manually add the training plan to the site. When you manually add a training plan to a site, its associated training topics are automatically added to the site. However, if the administrator populates

the Obsolete Date field (in the Training Topics view of the Administration - Clinical screen) for some topics in that plan, then those topics are not automatically added to the site even though the topics exist in the training plan.

The contacts for a clinical site are automatically associated with the training topics in the training plans that you add to the site if a Role field value in the topics is the same as the Role field value in the contact records. If the Role field in a topic of an added plan has no value, then all of the contacts for the clinical site are automatically associated with that topic.

You can add to clinical sites only the versions of training plans for which:

- The Obsolete Date field of the training plan has no value.
- The Status field for the version of the training plan has a value of Approved.

To add training plans to a clinical site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to add training plans.
3. Navigate to the Training view.
4. To add training plans, complete the following steps:
   a. Click Add Plans.
   b. In the Training Plans dialog box that appears, select the training plans to add.

      To select multiple plans, hold down the CTRL key and click each plan record. For information about setting up the training plans that appear in this dialog box, see *Creating Training Plans*.
   c. Click OK.

      The training topics associated with the selected training plans appear in the Site Training Status list.

Changing Training Topics for Clinical Sites

When administrators publish training plans, the training topics in those plans are automatically associated with the clinical sites that meet the criteria in the plans. When additional training topics apply to a site, you can manually add these topics to the automatically-added topics.

The contacts for a clinical site are automatically associated with the training topics that you add to the site if a Role field value in the topics is the same as the Role field value in the contact records. If the Role field in an added topic has no value, then all of the contacts for the clinical site are automatically associated with that topic.

You can add to clinical sites only the training topics for which the Obsolete Date field of the training topic has no value.

When training topics no longer apply to a site, you can delete the topics if the Mandatory field is not selected for the topics. You cannot change the field values in training topic records for clinical sites.

To change training topics for a clinical site

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to change training topics.
3. Navigate to the Training view.
4. To add training topics, complete the following steps:

a. Click Add Topics.
b. In the Training Topics dialog box that appears, select the training topics to add.

   To select multiple topics, hold down the CTRL key and click each topic record. For information about setting up the training topics that appear in this dialog box, see *Setting Up Training Topics for Clinical Training*.
c. Click OK.

   The selected topics appear in the Site Training Status list.

5. To delete a training topic, select the topic in the Site Training Status list, and delete it.

Designating Completed Training for Training Topics

In Siebel Clinical, you can access the training topics for clinical sites, and then designate when the contacts who are associated with those topics complete those topics. A contact is associated with only the topics that have no value in the Role field or a Role field value that is the same as the Role field value in the contact record. If you change the Role field value for a contact after the contact is associated with training topics, then the incomplete training topics for the contact can automatically change to accommodate the new role.

To designate completed training for training topics

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to designate completed training for training topics.
3. Navigate to the Training view.
4. In the Site Training Status list, select the appropriate training topic.
5. Complete one of the following steps:
   - If you want to designate that training is complete for all contacts associated with the training topic, then in the Site Training Status list click Complete All.

     In the Site Training Status list, the Contacts Completed field and the Contacts Not Completed field are automatically updated for the training topic. Also, for all contacts in the Contacts list, the Completed field is selected and the Completed Date field is populated with the current date and time.
   - If you want to designate that training is complete for selected contacts associated with the training topic, then in the Contacts list select the Completed field for those contacts.

     In the Site Training Status list, the Contacts Completed field and the Contacts Not Completed field are automatically updated for the training topic. Also, in the Contacts list, the Completed Date field is populated with the current date and time for those contacts for which you select the Completed field and save the contact record.

   If you want to reverse your designation of completed training for a contact, then clear the Completed field for the contact.
6. (Optional) In the Contacts list, complete the following steps for the appropriate contacts:
   a. Enter comments about the completed training.
   b. Change the value in the Completed Date field from the date and time when you designate that training is complete to the date and time that the contact actually completed the training.

Designating Completed Training for Contacts

In Siebel Clinical, you can access the contacts for clinical sites, and then designate when the contacts complete the training topics assigned to them. A contact is associated with only the topics that have no value in the Role field or a Role field value that is the same as the Role field value in the contact record. If you change the Role field value for a contact after the contact is associated with training topics, then the incomplete training topics for the contact can automatically change to accommodate the new role.

To designate completed training for contacts

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to designate completed training for contacts.
3. Navigate to the Contacts view.
4. In Contacts list, select the appropriate contact.
5. Complete one of the following steps:

    - If you want to designate that training is complete for all training topics associated with the contact, then in the Training Topics list click Complete All.

      In the Contacts list, the Trainings Completed field is automatically updated to show the number of training topics that the contact completed. Also, for all topics in the Training Topics list, the Completed field is selected and the Completed Date field is populated with the current date and time.
    - If you want to designate that training is complete for selected training topics associated with the contact, then in the Training Topics list select the Completed field for those training topics.

      In the Contacts list, the Trainings Completed field is automatically updated to show the number of training topics that the contact completed. Also, in the Training Topics list, the Completed Date field is populated with the current date and time for those topics for which you select the Completed field and save the contact record.
    - If you want to designate that training is complete for most training topics associated with the contact, then in the Training Topics list click Complete All, and clear the Completed field for the few training topics that the contact did not complete.

      In the Contacts list, the Trainings Completed field is automatically updated to show the number of training topics that the contact completed. Also, in the Training Topics list, the Completed Date field is populated with the current date and time for the topics in which the Completed field is selected.
6. (Optional) In the Training Topics list, complete the following steps for the appropriate training topics:

    a. Enter comments about the completed training.
    b. Change the value in the Completed Date field from the date and time when you designate that training is complete to the date and time that the contact actually completed the training.

Viewing Training Information for Clinical Protocols

When administrators publish training plans, the training topics in those plans are automatically associated with the clinical sites that meet the criteria in the plans. Each site is associated with a clinical protocol. When users designate completed training for the training topics or for the contacts of a clinical site, the training completion details are summarized and rolled up to the associated clinical protocol. Complete the procedure in this topic to view the progress of site training for a clinical protocol.

To view the training information for a clinical protocol

1. Navigate to the Protocols screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol for which you want to view training information.
3. Navigate to the Training view.
4. Click Refresh to update the view with the latest information about completed training.
5. Review the training information in the training overview applet.

   Some fields are described in the following table.

Field	Comments
Total Trainings	Displays the total number of training topics for the protocol. Each of these topics appears in the training details applet.
Trainings Completed	Displays the number of training topics that all associated contacts completed for all the sites in the protocol.
Sites Completed	Displays the number of sites in the protocol for which all associated contacts completed all the training topics.

6. Review the training information in the training details applet.

   Some fields are described in the following table.

Field	Comments
Topic Name	Displays the training topic name for the protocol. If a topic associated with a site record for the protocol does not apply to any contacts for the protocol, then that topic does not appear in the training details applet.
Sites Completed	Displays the number of sites in the protocol for which all associated contacts completed the training topic.

Field	Comments
Sites Not Completed	Displays the number of sites in the protocol for which all associated contacts have not completed the training topic.

Viewing Training Information for Clinical Regions

When administrators publish training plans, the training topics in those plans are automatically associated with the clinical sites that meet the criteria in the plans. Each site can be associated with a clinical region. When users designate completed training for the training topics or for the contacts of a clinical site, the training completion details are summarized and rolled up to the associated clinical region if such a region exists. Complete the procedure in this topic to view the progress of site training for a clinical region.

To view the training information for a clinical region

1. Navigate to the Regions screen, then the Region List view.
2. In the Region list, drill down on the Region field of the region for which you want to view training information.
3. Navigate to the Training view.
4. Click Refresh to update the view with the latest information about completed training.
5. Review the training information in the training overview applet.
   Some fields are described in the following table.

Field	Comments
Total Trainings	Displays the total number of training topics for the region. Each of these topics appears in the training details applet.
Trainings Completed	Displays the number of training topics that all associated contacts completed for all the sites in the region.
Sites Completed	Displays the number of sites in the region for which all associated contacts completed all the training topics.

6. Review the training information in the training details applet.
   Some fields are described in the following table.

Field	Comments
Topic Name	Displays the training topic name for the region. If a topic associated with a site record for the region does not apply to any contacts for the region, then that topic does not appear in the training details applet.

Field	Comments
Sites Completed	Displays the number of sites in the region for which all associated contacts completed the training topic.
Sites Not Completed	Displays the number of sites in the region for which all associated contacts have not completed the training topic.

12 Siebel Clinical Task-Based UI

Siebel Clinical Task-Based UI

This chapter describes the task-based user interface for Siebel Clinical which CRAs (clinical research associates) use to manage protocols, regions, and sites for clinical studies. It includes the following topics:

Note: Siebel Clinical task-based UI is available in Siebel CRM 20.7 Update and later releases.

About Siebel Clinical Task-Based UI

There are many tasks that CRAs perform in Siebel Clinical to manage protocols, regions, and sites for clinical studies. These tasks involve going to multiple screens in Siebel Clinical and performing subtasks in a specific order, which can be very time consuming and confusing for CRAs unfamiliar with the process. The purpose of Siebel Clinical task-based UI is to ensure a standard process for managing studies and site entries across an organization whereby when users open the task-based UI, they can navigate (forward and backward) through multiple screens to perform key clinical tasks and pause and resume job tasks as required. Validation is used to enforce any rules required by business processes – for example, you can create a site with or without a region.

The task-based UI for Siebel Clinical guides you through a series of steps to complete the following key clinical tasks:

1. Create a Protocol.

2. Create a Protocol and Region.
3. Create a Site.
4. Create Site Contacts.
5. Create Activity Plans for sites, exiting protocols, and existing regions.
6. Create Risk Assessments for sites, existing protocols, existing regions, and existing programs.
7. Go to Inbox to review inbox tasks, transfer tasks, and delete tasks as required.

Activating Siebel Clinical Task-Based UI

The following procedure shows how to activate the task-based UI for Siebel Clinical.

To activate Siebel Clinical task-based UI

1. In Siebel Clinical, navigate to the Administration - Business Process screen, then the Task Deployment view.
2. In the Published Tasks list, query for `Ls Clinical*` in the Name field.
3. Click Activate (in the Published Tasks list).

   Siebel CRM validates the format and then changes the deployment status of the `Ls Clinical*` task UI to Active.
4. Go to the Active Tasks list and verify that the Deployment Status field of the `Ls Clinical*` task UI displays a value of Active.

Accessing Siebel Clinical Task-Based UI

The following procedure shows how to access the task-based UI for Siebel Clinical.

To access Siebel Clinical task-based UI

1. Click Tasks on the application taskbar to open the Tasks applet for Siebel Clinical.
2. In the Tasks applet, the following predefined clinical tasks are available:
   a. **Create Protocol.** Click to create a new protocol and (if required) region:
      - *Creating Protocols*
      - *Creating Protocols and Regions*
   b. **Create Site.** Click to create a new site - see *Creating Sites*.
   c. **Other Site Tasks.** Click to perform the following tasks on new or existing sites:
      - *Creating Site Contacts*
      - *Creating Activity Plans for Sites*
      - *Creating RACT Assessments for Sites*
   d. **Other Protocol Tasks.** Click to perform the following tasks on existing protocols:
      - *Creating Activity Plans for Existing Protocols*
      - *Creating RACT Assessments for Existing Protocols*
   e. **Other Region Tasks.** Click to perform the following tasks on existing regions:

- *Creating Activity Plans for Existing Regions*
- *Creating RACT Assessments for Existing Regions*

f. **Other Program Tasks.** Click to perform the following task on existing programs:

- *Creating RACT Assessments for Existing Programs*

3. Click Go to Inbox to go to the Inbox Items List view where you can resume work on paused tasks, transfer tasks, and delete tasks - see *Administering Inbox Tasks*.

Assigning Responsibilities to Predefined Task-Based UI Clinical Tasks

By default, Siebel Clinical administrators can access all the predefined task-based UI clinical tasks. To assign another responsibility to one or all of the predefined clinical tasks, then complete the steps in the following procedure.

To assign a responsibility to a predefined task-based UI clinical task

1. Navigate to the Administration – Application screen, then the Tasks view.
2. In the Registered Tasks list, query for `LS Clinical*` in the Task Name field. The following list of Registered tasks for Siebel Clinical returns.

   - LS Clinical TUI Create New Protocol
   - LS Clinical TUI Create New Site
   - LS Clinical TUI Create Other Site Task
   - LS Clinical TUI Protocol Tasks
   - LS Clinical TUI Program Other Tasks
   - LS Clinical TUI Region Other Tasks

   Notice that the Siebel Administrator responsibility (with Allow Delete and Allow Transfer permission) is assigned to each of these tasks by default.
3. Do the following to assign a new responsibility to, for example, the LS Clinical TUI Create New Site task:

   a. In the Registered Tasks list, select LS Clinical TUI Create New Site.
   b. In the Responsibilities list, click the plus (+) icon and then query for `Clinical*` in the Name field.
   c. Select Clinical Manager and then click OK.

   The Clinical Manager responsibility (with Allow Delete and Allow Transfer permission) now appears in the Responsibilities list for LS Clinical TUI Create New Site.
4. Repeat step 3, as required, to add other responsibilities to `LS Clinical*` tasks.

Creating Protocols

The following procedure shows how to create a protocol using Siebel Clinical task-based UI.

To create a protocol

1. Click Tasks on the application taskbar to open the Tasks applet for Siebel Clinical.
2. Click Create Protocol in the Tasks applet.
3. Enter protocol data on the page that appears - the fields are described in the following table.

Field	Description
Program	Select the name of the program for the clinical trial.
Product	Select the product for the clinical trial. You can select only the products that are associated with the clinical program.
# Planned Sites	Type the number of planned sites for the protocol.
# Planned Subjects	Type the number of planned subjects for the protocol.
Regions Required	Select this check box only if the sites for the protocol must belong to a region (and see *Creating Protocols and Regions* for more information). When you select this check box, you cannot create sites directly under protocols. You must create regions first, and then create sites that are associated with regions. Deselect this check box to indicate that the sites for this protocol must not belong to a region.
Protocol #	Type an identifying number for the protocol.
Phase	Select the phase of clinical trial, such as, Phase I, II, or III.
Status	Select the protocol status, such as, Planned, In Progress, or Completed.
Type	Select the purpose of the protocol.
Title	Type a descriptive title for the protocol.

4. If required, click Pause at any time to pause the task.

   The task moves to your Inbox where you must go when you want to resume work on the task.
5. If required, click Cancel at any time to cancel the task.
6. Click Submit to submit the task - that is, create the new protocol.

Creating Protocols and Regions

The following procedure shows how to create a protocol and region using Siebel Clinical task-based UI.

To create a protocol and region

1. Click Tasks on the application taskbar to open the Tasks applet for Siebel Clinical.
2. Click Create Protocol in the Tasks applet.
3. Enter protocol data on the page that appears:
    - Fields to complete are described in *Creating Protocols*.
    - Select the Regions Required check box.
4. Click Submit.
5. Click Yes when prompted with the following question: *Do you want to create Region now?*
6. Click Submit.
7. Enter regional data on the page that appears - the fields are described in the following table.

Field	Description
Region	Select the geographical region to which the protocol belongs.
Protocol Region	Displays the name of the region. This field is automatically populated with the protocol number and region name.
Status	Select the region status. Options include Planned, In Progress, Completed, or Terminated,
Central Lap	Select the Account name to assign the associated central lab.
CRO	Select the Account name to assign the associated CRO.
# Planned Sites	Type the number of planned sites for the region.
# Planned Subjects	Type the number of planned subjects for the region.
Currency Code	Select the currency that will be used to display the payments, costs, and budgets for the region. The default value is USD (US dollars).
Withholding Amount	Type the amount to withhold from each of the payments to the investigators until the trial completes.

Field	Description
Withholding Percent (%)	Type the percentage to withhold from each of the payments to investigators until the trial is complete.
Exchange Date	Select the date that determines the exchange rate of the currency. By default, the exchange date for the region is the date that you create the region.
No Site Info	Select this option to indicate that no site information will be available under the region. In such cases, only summary information about site enrolment will be available for the region. Deselect this option to indicate that site information will be available under the region.

8. If required, click Pause at any time to pause the task.

   The task moves to your Inbox where you must go when you want to resume work on the task.
9. If required, click Cancel at any time to cancel the task.
10. Click Submit to submit the task - that is, create the new protocol and region.

Creating Sites

The following procedure shows how to create a site using Siebel Clinical task-based UI.

To create a site

1. Click Tasks on the application taskbar to open the Tasks applet for Siebel Clinical.
2. Click Create Site in the Tasks applet.
3. Enter site data on the page that appears - the fields are described in the following table.

Field	Description
Protocol #	Type an identifying number for the protocol.
Region	Select the geographical region to which the site belongs.
Site #	Type the number to assign to the site.
PI Last Name	Select the last name of the principal investigator for the site.

Field	Description
PI First Name	The first name of the principal investigator for the site (read-only field).
# Planned Subjects	Type the number of planned subjects for the protocol.
SDV Policy	Select the Source Data Verification Policy.
Activity Plans	Select Yes if you want to create activity plans for this site, otherwise select No.
Site Contacts	Select Yes if you want to create contacts for this site, otherwise select No.
RACT Assessment	Select Yes if you want to create risk assessments for this site, otherwise select No.

4. If required, click Pause at any time to pause the task.
   The task moves to your Inbox where you must go when you want to resume work on the task.
5. If required, click Cancel at any time to cancel the task.
6. Click Submit to do one of the following:
   a. Submit the task - that is, create the site.
   b. Create site contacts, activity plans, and/or risk assessments for the site. For more information, see the following topics:
      - *Creating Site Contacts*
      - *Creating Activity Plans for Sites*
      - *Creating RACT Assessments for Sites*

Creating Site Contacts

The following procedure shows how to create a site contact using Siebel Clinical task-based UI.

To create a site contact

1. Click Tasks on the application taskbar to open the Tasks applet for Siebel Clinical.
2. Complete one of the following to create a site contact for a new or an existing site:
   a. To create a site contact for a new site:
      - Click Create Site in the Tasks applet.
      - Enter site data on the page that appears - all fields are described in *Creating Sites*.
      - Select Yes for Site Contacts and then click Submit.
   b. To create a site contact for an existing site:

- Click Other Site Tasks in the Tasks applet.
- Select the record that you want in the Sites list and then click Submit.
- Select Yes for Site Contacts and then click Submit.

3. Enter site contact details on the page that appears - some fields are described in the following table.

Field	Description
Role	The role of the contact.
Last Name	The first name of the contact.
First Name	The last name of the contact.
Start Date	The date when the contact record is active.
Address	The address for the contact.
City	The city where the contact is located.
State	The state where the contact is located.
Postal Code	The postal code for the contact's address.
Country	The country where the contact is located.
Main Phone	The phone number for the contact.
E-Mail	The email address for the contact.

4. If required, click the plus (+) icon to create additional site contacts.
5. If required, click Pause at any time to pause the task.

   The task moves to your Inbox where you must go when you want to resume work on the task.
6. If required, click Cancel at any time to cancel the task.
7. Click the check box next to each contact that you want to associate with the site and then click Submit to submit the task - that is, create the site contact(s).

Creating Activity Plans for Sites

The following procedure shows how to create activity plans for a site using Siebel Clinical task-based UI.

To create an activity plan for a site

1. Click Tasks on the application taskbar to open the Tasks applet for Siebel Clinical.
2. Complete one of the following to create an activity plan for a new or an existing site.
   a. To create an activity plan for a new site:
      - Click Create Site in the Tasks applet.
      - Enter site data on the page that appears - all fields are described in *Creating Sites*.
      - Select Yes for Activity Plans and then click Submit.
   b. To create an activity plans for an existing site:
      - Click Other Site Tasks in the Tasks applet.
      - Select the record that you want in the Sites list and then click Submit.
      - Select Yes for Activity Plans and then click Submit.
3. Enter activity plan details on the page that appears - some fields are described in the following table.

Field	Description
Planned Start	Select the date and time to start the activity plan.
Templates	Select the template for the activity plan.
Description	This field is automatically populated when you select a template for the activity plan.
Lock Assignment	Lock the assignment as required by selecting this field.

4. If required, click the plus (+) icon to create additional activity plans.
5. If required, click Pause at any time to pause the task.
   The task moves to your Inbox where you must go when you want to resume work on the task.
6. If required, click Cancel at any time to cancel the task.
7. Click the check box next to each activity plan that you want to associate with the site and then click Submit to submit the task - that is, create the activity plan(s) for the site.

Creating Activity Plans for Existing Protocols

The following procedure shows how to create activity plans for existing protocols using Siebel Clinical task-based UI.

To create an activity plan for an existing protocol

1. Click Tasks on the application taskbar to open the Tasks applet for Siebel Clinical.
2. Click Other Protocol Tasks in the Tasks applet.
3. Select the record that you want in the Protocols list and then click Next.
4. Select Yes for Activity Plans and then click Next.
5. Enter activity plan details on the page that appears - all fields are described *Creating Activity Plans for Sites*.
6. If required, click the plus (+) icon to create additional activity plans.
7. If required, click Pause at any time to pause the task.

   The task moves to your Inbox where you must go when you want to resume work on the task.
8. If required, click Cancel at any time to cancel the task.
9. Click the check box next to each activity plan that you want to associate with the protocol and then click Submit to submit the task - that is, create the activity plan(s) for the protocol.

Creating Activity Plans for Existing Regions

The following procedure shows how to create activity plans for existing regions using Siebel Clinical task-based UI.

To create an activity plan for an existing region

1. Click Tasks on the application taskbar to open the Tasks applet for Siebel Clinical.
2. Click Other Region Tasks in the Tasks applet.
3. Select the record that you want in the Regions list and then click Submit.
4. Select Yes for Activity Plans and then click Submit.
5. Enter activity plan details on the page that appears - all fields are described *Creating Activity Plans for Sites*.
6. If required, click the plus (+) icon to create additional activity plans.
7. If required, click Pause at any time to pause the task.

   The task moves to your Inbox where you must go when you want to resume work on the task.
8. If required, click Cancel at any time to cancel the task.
9. Click the check box next to each activity plan that you want to associate with the region and then click Submit to submit the task - that is, create the activity plan(s) for the region.

Creating RACT Assessments for Sites

The following procedure shows how to create risk assessments for a site using Siebel Clinical task-based UI.

To create a risk assessment for a site

1. Click Tasks on the application taskbar to open the Tasks applet for Siebel Clinical.

2. Complete one of the following to create a risk assessment for a new or an existing site.
   a. To create a risk assessment for a new site:
      - Click Create Site in the Tasks applet.
      - Enter site data on the page that appears - all fields are described in *Creating Sites*.
      - Select Yes for RACT Assessment and then click Submit.
   b. To create a risk assessment for an existing site:
      - Click Other Site Tasks in the Tasks applet.
      - Select the record that you want in the Sites list and then click Submit.
      - Select Yes for RACT Assessment and then click Submit.
3. Enter risk assessment details on the page that appears as follows:
   - In the Assessments Templates applet, select the assessment template in the Template Name field.
   - If required, click the plus (+) icon to create additional assessment template records.
   - In the Assessment Questions applet, complete the necessary fields for each question that you want to assess. For more information, see *Creating Risk Assessment Templates*.
4. If required, click Pause at any time to pause the task.

   The task moves to your Inbox where you must go when you want to resume work on the task.
5. If required, click Cancel at any time to cancel the task.
6. Click the check box next to each assessment template and assessment question that you want to associate with the site and then click Submit to submit the task - that is, create the risk assessment(s) for the site.

Creating RACT Assessments for Existing Protocols

The following procedure shows how to create risk assessments for existing protocols using Siebel Clinical task-based UI.

To create a risk assessment for an existing protocol

1. Click Tasks on the application taskbar to open the Tasks applet for Siebel Clinical.
2. Click Other Protocol Tasks in the Tasks applet.
3. Select the record that you want in the Protocols list and then click Next.
4. Select Yes for RACT Assessment and then click Next.
5. Enter risk assessment details on the page that appears as follows:
   - In the Assessments Templates applet, select the assessment template in the Template Name field.
   - If required, click the plus (+) icon to create additional assessment template records.
   - In the Assessment Questions applet, complete the necessary fields for each question that you want to assess. For more information, see *Creating Risk Assessment Templates*.
6. If required, click Pause at any time to pause the task.

   The task moves to your Inbox where you must go when you want to resume work on the task.
7. If required, click Cancel at any time to cancel the task.
8. Click the check box next to each assessment template and assessment question that you want to associate with the protocol and then click Submit to submit the task - that is, create the risk assessment(s) for the protocol.

Creating RACT Assessments for Existing Regions

The following procedure shows how to create risk assessments for existing regions using Siebel Clinical task-based UI.

To create a risk assessment for an existing region

1. Click Tasks on the application taskbar to open the Tasks applet for Siebel Clinical.
2. Click Other Region Tasks in the Tasks applet.
3. Select the record that you want in the Regions list and then click Submit.
4. Select Yes for RACT Assessment and then click Submit.
5. Enter risk assessment details on the page that appears as follows:
    - In the Assessments Templates applet, select the assessment template in the Template Name field.
    - If reqruied, click the plus (+) icon to create additional assessment template records.
    - In the Assessment Questions applet, complete the necessary fields for each question that you want to assess. For more information, see *Creating Risk Assessment Templates*.
6. If required, click Pause at any time to pause the task.

   The task moves to your Inbox where you must go when you want to resume work on the task.
7. If required, click Cancel at any time to cancel the task.
8. Click the check box next to each assessment template and assessment question that you want to associate with the region and then click Submit to submit the task - that is, create the risk assessment(s) for the region.

Creating RACT Assessments for Existing Programs

The following procedure shows how to create risk assessments for existing programs using Siebel Clinical task-based UI.

To create a risk assessment for an existing program

1. Click Tasks on the application taskbar to open the Tasks applet for Siebel Clinical.
2. Click Other Program Tasks in the Tasks applet.
3. Select the record that you want in the Programs list and then click Submit.
4. Select Yes for RACT Assessment and then click Submit.
5. Enter risk assessment details on the page that appears as follows:
    - In the Assessments Templates applet, select the assessment template in the Template Name field.
    - If required, click the plus (+) icon to create additional assessment template records.
    - In the Assessment Questions applet, complete the necessary fields for each question that you want to assess. For more information, see *Creating Risk Assessment Templates*.
6. If required, click Pause at any time to pause the task.

   The task moves to your Inbox where you must go when you want to resume work on the task.
7. If required, click Cancel at any time to cancel the task.

8. Click the check box next to each assessment template and assessment question that you want to associate with the program and then click Submit to submit the task - that is, create the risk assessment(s) for the program.

Administering Inbox Tasks

You can pause a clinical task at any time and resume work on the task, as required, by going to the the Inbox Items List view of Siebel Clinical task-based UI. You can also delete and transfer tasks in the Inbox Items List view as shown in the following procedure.

To administer Inbox tasks for Siebel Clinical task-based UI

1. Click Tasks on the application taskbar to open the Tasks applet for Siebel Clinical.
2. Click Go to Inbox in the Tasks applet.

   The Inbox Items List view appears.
3. To resume work on a task:

   a. Drill down on the task (Name field) that you want to resume work on.
   b. Resume work on the task and complete the task as required.
4. To transfer a task:

   a. Select a task in the Inbox Items List.
   b. Click Transfer.
   c. In the Transfer To dialog that appears, select the user to whom you want to transfer the task.
   d. Enter a comment in the Comments box to notify the user and then click OK.
5. To delete a task:

   a. Select a task in the Inbox Items List.
   b. Click Delete Task.

13 Supporting Blinded and Unblinded Users for Clinical Trials

Supporting Blinded and Unblinded Users for Clinical Trials

This chapter describes blinded and unblinded support in Siebel Clinical, how to control access to data for blinded and unblinded users, and how to administer blinded and unblinded users for clinical trials. It includes the following topics:

- *What is a Blinded and Unblinded Clinical Trial?*
- *Blinded and Unblinded Support in Siebel Clinical*
- *Controlling Access to Data for Blinded and Unblinded Users*
- *Site Management for Blinded and Unblinded Users*
- *Inheritance Hierarchy for Blinded and Unblinded Users*
- *Blinded and Unblinded Support in Siebel Mobile Disconnected Applications*
- *Blinded and Unblinded Customization Support*

Note: This feature is available in Siebel CRM 20.7 Update and later releases.

What is a Blinded and Unblinded Clinical Trial?

A *blinded* clinical trial is one where participants do not know which treatment or medical intervention they have been allocated. In a blind clinical trial, certain information which may influence the participants in the trial (including subjects, CRAs, and evaluators) is withheld or hidden (blinded) until after the trial is complete. Good blinding can reduce or eliminate experimental biases that arise from participant expectation, observer bias, confirmation bias, and so on.

An *unblinded* clinical trial is one where information is not withheld from trial participants and, in such cases, both participants and researchers know which treatment is being administered. During the course of a clinical trial, a participant becomes unblinded if they obtain information that has been withheld or hidden (blinded) from them. However, if this occurs unintentionally before the end of the trial, then this can be a source of experimental error.

Blinded and Unblinded Support in Siebel Clinical

Siebel Clinical provides the option to have and the ability to manage both blinded and unblinded users for clinical trials in Siebel CRM 20.7 Update and later releases.

Key issues to note about blinded and unblinded support in Siebel Clinical include the following:

1. All users are blinded by default in Siebel Clinical Trial Management System (CTMS).
   - Blinded users can view blinded data.

     Blinded users cannot view unblinded data in Site Visits and Activities.
   - Unblinded users can view unblinded data.

     Unblinded users can either view blinded data in Site Visits and Activities in read-only mode (this is the default behavior) based on a study level preference setting or they cannot view blinded data in Site Visits and Activities at all. The study level preference setting, **`Hide blinded content for unblinded users`**, is controlled by the Siebel Clinical administrator – see *Controlling Access to Blinded Data for Unblinded Users* for more information.
2. The Siebel Clinical administrator can associate either blinded or unblinded users to the study team at the protocol, region, or site level.
3. A user can be blinded at some sites and unblinded at others in the same study, and this is controlled by the Siebel Clinical administrator.
4. Site Visits, Activities, and Document Tracking created by blinded users are blinded.
5. Site Visits, Activities, and Document Tracking created by unblinded users are unblinded.

Controlling Access to Data for Blinded and Unblinded Users

Access control is the term used to describe the set of Siebel application mechanisms that control user access to data and application functionality. Controlling access to data for blinded and unblinded users involves the following tasks:

- *Controlling Access to Blinded Data for Unblinded Users*
- *Setting Blinded and Unblinded User Access at Protocol Level*
- *Setting Blinded and Unblinded User Access at Region Level*
- *Setting Blinded and Unblinded User Access at Site Level*
- *Setting Access to Unblinded Activities in Core Activities View and Contact Activities View*

Controlling Access to Blinded Data for Unblinded Users

Unblinded users by default see both blinded data and unblinded data, where blinded data is displayed in read-only mode. However, administrators can modify this default behaviour by changing the protocol level setting **`Hide blinded content for unblinded users`**.

Access to blinded data by unblinded users is controlled by the protocol level setting **`Hide blinded content for unblinded users`**. This setting is deselected (set to N) by default in Siebel Clinical, can be changed only by the Siebel Clinical administrator, and is configured at the protocol level.

To configure access to blinded data for unblinded users

1. Navigate to the Administration - Clinical screen, then the Protocol List view.
2. In the Protocol list, drill down on a protocol number field.

3. Configure the `Hide blinded content for unblinded users` check box as required as shown in the following table.

Setting (Check box)	Value	Description
Hide blinded content for unblinded users	N (Deselected, default setting)	Indicates that unblinded users can view blinded data, like Site Visits and Activities, in read-only mode. This is the default behaviour.
	Y (Selected)	Indicates that unblinded users cannot view blinded data, such as Site Visits and Activities.

Setting Blinded and Unblinded User Access at Protocol Level

The following procedure shows how administrators configure blinded or unblinded user access for protocol team members.

To set blinded or unblinded user access at protocol level

1. Navigate to the Administration - Clinical screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol (number field) for which you want to configure the blinded or unblinded user access.
3. Click the multiple select button in the Team field.

   A multiple selection dialog box appears showing a list of the available and selected protocol team members (users).
4. For each user in the Selected list that should have unblinded protocol level access, configure the Unblinded field as shown in the following table.

Field	Value	Description
Unblinded	N or Null (Deselected, default setting)	Deselect this option to make the user blinded. All users are blinded by default.
	Y (Selected)	Select this option to make the user unblinded. Unblinded users are highlighted in the color red.

5. Click OK when prompted to confirm the update in the Unblinded field.
6. If required at protocol level, click Position Rolldown to roll down the changes to all the regions and sites for the protocol. The position roll down hierarchy goes from Protocol, to Region, and then to Site level.

Setting Blinded and Unblinded User Access at Region Level

All users within a region will inherit the same blinded or unblinded user access that they have at the protocol level provided the position was rolled down from the protocol team to the site level. For newly created regions, administrators can either:

- Go back to the required protocol and click Position Rolldown to roll down the protocol team user access to the region level.
- Directly configure blinded or unblinded user access for region team members as shown in the following procedure.

To set blinded or unblinded user access at region level

1. Navigate to the Administration - Clinical screen, then the Region List view.
2. In the Region list, drill down on the region for which you want to configure the blinded or unblinded user access.
3. Click the multiple select button in the Team field.

   A multiple selection dialog box appears showing a list of the available and selected region team members (users).
4. For each user in the Selected list that should have unblinded region level access, configure the Unblinded field as shown in the following table.

Field	Value	Description
Unblinded	N or Null (Deselected, default setting)	Deselect this option to make the user blinded. All users are blinded by default.
	Y (Selected)	Select this option to make the user unblinded. Unblinded users are highlighted in the color red.

5. Click OK when prompted to confirm the update in the Unblinded field.
6. If required at region level, click Position Rolldown to roll down the changes to all the sites for the region. The position roll down hierarchy goes from Protocol, to Region, and then to Site level.

Setting Blinded and Unblinded User Access at Site Level

All users within a site will inherit the same blinded and unblinded user access that they have at the protocol or region level provided the position was rolled down from the protocol or region team to the site level. For newly created sites, administrators can either:

- Go back to the required protocol or region and click Position Rolldown to roll down the protocol or region team user access to the site level.
- Directly configure blinded and unblinded user access for site users as shown in the following procedure.

  Precedence is given to configuration of blinded and unblinded user access at site level. If the blinded and unblinded user access is updated at site level, then position roll down from protocol and/or region cannot override the definition at site level, since site has more precedence.

To set blinded and unblinded user access at site level

1. Navigate to the Administration - Clinical screen, then the Site List view.
2. In the Site list, drill down on the site for which you want to configure the blinded and unblinded user access.
3. Click the multiple select button in the Team field.

   A multiple selection dialog box appears showing a list of the available and selected site team members (users).
4. For each user in the Selected list that should have unblinded site level access, configure the Unblinded field as shown in the following table.

Field	Value	Description
Unblinded	N or Null (Deselected, default setting)	Deselect this option to make the user blinded. All users are blinded by default.
	Y (Selected)	Select this option to make the user unblinded. Unblinded users are highlighted in the color red.

5. Click OK when prompted to confirm the update in the Unblinded field.
6. If required at site level, click Position Rollup to update the Unblinded field for users at protocol and region levels. The position roll up hierarchy goes from Site, to Region, and then to Protocol level.

Setting Access to Unblinded Activities in Core Activities View and Contact Activities View

All users are blinded by default in Siebel Clinical, which means that users can typically see only unblinded activities. However, if a user is assigned the Unblinded Activity Responsibility (a responsibility assigned to Siebel Clinical administrators by default), then that user will have access to unblinded activities in Siebel Clinical core Activities view and Contact Activities view.

To set access to unblinded activities in core Activities View and Contact Activities views

1. Log in to Siebel Tools.
2. Go to Business Component and query for the name `Action`.
3. Go to the Business Component User Properties for the Action business component.
4. Query for the name `Unblinded Activity Responsibility`.
5. Update the Value field for Unblinded Activity Responsibility by adding the required user roles (or responsibilities) to it.

   These user roles will be able to view unblinded data in Siebel Clinical core Activities and Contact Activities views. Siebel Administrator is mapped by default to the Unblinded Activity Responsibility business component user property.

Site Management for Blinded and Unblinded Users

Site management for blinded and unblinded users involves the following:

- *Identifying Type of User Access at Protocol Site*
- *Document Tracking for Sites*
- *Managing Site Activities for Blinded and Unblinded Users*
- *Managing Site Activity Plans for Blinded and Unblinded Users*
- *Managing Site Visits for Blinded and Unblinded Users*
- *Managing All Site Visits for Blinded and Unblinded Users*
- *Managing BIP Reports for Blinded and Unblinded Users*
- *Managing Activities for Blinded and Unblinded Users*
- *Managing Contact Activities for Blinded and Unblinded Users*

Identifying Type of User Access at Protocol Site

A user can be blinded at one site and unblinded at another site in the same study. The User indication bar in the form toolbar of a selected site helps users identify the type of user access they have to a site.

To identify type of user access at protocol site

1. Navigate to the Site Management screen, then the Protocol Site list view.
2. In the Protocol Site list view, drill down on a site.
3. Review the User indication bar in the form toolbar of the selected site as follows:
    - A red User indication bar, labelled Blinded when you hover over it, indicates that the user access to the site is blinded.
    - A green User indication bar, labelled Unblinded when you hover over it, indicates that the user access to the site is unblinded.

Document Tracking for Sites

You administer document tracking for sites by navigating to the Site Management screen, Protocol Site list view, drilling down on a Site, and then navigating to the Document Tracking view.

From the Document Tracking view for a site, you can create new document tracking records. Note the following about document tracking for sites for blinded and unblinded users:

- Document tracking records created by unblinded users are unblinded. In this case, the Unblinded field for each unblinded record is selected (Unblinded=Y) and the record is highlighted in the color red.
- Document tracking records created by blinded users are blinded. In this case, the Unblinded field for each blinded record is deselected (Unblinded=N or Null).

- Unblinded users can either view blinded document tracking records in read-only mode (depending on the protocol level setting `Hide blinded content for unblinded users`) or cannot view blinded document tracking records at all.
- Blinded users cannot view unblinded document tracking records.

Managing Site Activities for Blinded and Unblinded Users

You manage activities for a site by navigating to the Site Management screen, Protocol Site list view, drilling down on a Site, and then navigating to the Activities view.

From the Activities view for a site, you can create new site activities. Note the following about managing site activities for blinded and unblinded users:

- Activities created by unblinded users are unblinded. In this case, the Unblinded field for each unblinded activity record is selected (Unblinded=Y) and the activity is highlighted in the color red.
- Activities created by blinded users are blinded. In this case, the Unblinded field for each blinded activity record is deselected (Unblinded=N or Null).
- Unblinded users can either view blinded activites in read-only mode (depending on the protocol level setting `Hide blinded content for unblinded users`) or cannot view blinded activities at all.
- Blinded users cannot view unblinded activities.
- Blinded users cannot be added as an employee to an unblinded site activity.

Managing Site Activity Plans for Blinded and Unblinded Users

You manage activity plans for a site by navigating to the Site Management screen, Protocol Site list view, drilling down on a Site, and then navigating to the Activity Plans view.

From the Activity Plans view for a site, you can create new activity plans. Note the following about managing activity plans for blinded and unblinded users:

- Activity Plans created by unblinded users are unblinded. In this case, the Unblinded field for each unblinded activity plan is selected (Unblinded=Y) and the activity is highlighted in the color red.
- Activity Plans created by blinded users are blinded. In this case, the Unblinded field for each blinded activity plan is deselected (Unblinded=N or Null).
- All Activities associated with unblinded activity plans are unblinded.
- All Activities associated with blinded activity plans are blinded.
- Unblinded users can either view blinded activity plans in read-only mode (depending on the protocol level setting `Hide blinded content for unblinded users`) or cannot view blinded activity plans at all.
- Blinded users cannot view unblinded Activity Plans and the associated unblinded activities.

Managing Site Visits for Blinded and Unblinded Users

You manage site visits by navigating to the Site Management screen, Protocol Site list view, drilling down on a Site, and then navigating to the Site Visits view.

From the Site Visits view, you can create new site visits. Note the following about managing site visits for blinded and unblinded users:

- Site Visits created by unblinded users are unblinded. In this case, the Unblinded field for each unblinded site visit is selected (Unblinded=Y) and the site visit is highlighted in the color red.
- Site Visits created by blinded users are blinded. In this case, the Unblinded field for each blinded site visit is deselected (Unblinded=N or Null).
- Unblinded users can either view blinded site visits in read-only mode (depending on the protocol level setting **`Hide blinded content for unblinded users`**) or cannot view blinded site visits at all.
- Blinded users cannot view unblinded Site visits and they:
  - Cannot be assigned to an unblinded Site Visit.
  - Cannot be assigned to Checklist Activities, Follow-up items or All follow-up activities of an unblinded trip report.
- When the protocol level setting **`Hide blinded content for unblinded users`** is not selected and an unblinded user has read-only access to blinded site visits, then the following conditions are true:
  - Trip report Checklist Activities are read-only.
  - Trip report Follow Up Activities are read-only.
  - Unblinded trip reports will show only unblinded records in the All follow Up Activities view.
  - Trip report Case Report Form Tracking is read-only.
  - The New File and New URL options in Site Visit Attachment is disabled.
- If the protocol level setting **`Hide blinded content for unblinded users`** is selected, then for unblinded users, unblinded trip reports will show only unblinded records in the All Follow Up Activities view.
- All versions of a blinded site visit will remain blinded, and all versions of an unblinded site visit will remain unblinded.

Managing All Site Visits for Blinded and Unblinded Users

You manage All Site Visits by navigating to the Administration - Clinical screen, then the Site Visits view.

This read-only view has a consolidated list of all site visits in the system, including blinded and unblinded site visits.

Managing Site BIP Reposts for Blinded and Unblinded Users

My BIP Reports shows all reports for reportees irrespective of user access (that is, whether users are blinded or unblinded). The My BIP Reports view does not apply for blinded users who have unblinded reportees. To ensure that blinded users who have unblinded reportees will not be able to see unblinded data, it is recommended that those blinded users should not be provided access to reoprts.

Managing Activities for Blinded and Unblinded Users

You manage activities by navigating to the Activities screen, then the All Activities view.

From the All Activities view, you can create new activities. Note the following about managing activities for blinded and unblinded users:

- By default, all users see only blinded activities in the All Activities view under Activities.
- Activities created directly in the All Activities view under Activities are blinded.

  > **Note:** Unblinded activities are created in the Activities view under a site (not in the All Activities view under Activities), for more information, see *Managing Site Activities for Blinded and Unblinded Users*.

- Users who are assigned the responsibility `Unblinded Activity Responsibility` can see both blinded and unblinded records in the All Activities view.
  - Siebel Clinical administrators are assigned the `Unblinded Activity Responsibility` by default.
  - To associate other user roles with the `Unblinded Activity Responsibility`, see *Setting Access to Unblinded Activities in Core Activities View and Contact Activities View*

Managing Contact Activities for Blinded and Unblinded Users

You manage contact activities by navigating to the Contacts screen, then the All Contacts view, drilling down on the Last Name of a contact, and then navigating to the Activities view.

From the Contact Activities view, you can create new contact activities. Note the following about managing contact activities for blinded and unblinded users:

- By default, all users see only blinded activities in the Activities view under Contacts.
- Activities created directly in the Activities view under Contacts are blinded.

  > **Note:** Unblinded activities are created in the Activities view under a site (not in the Activities view under Contacts), for more information, see *Managing Site Activities for Blinded and Unblinded Users*.

- Users who are assigned the responsibility `Unblinded Activity Responsibility` can see both blinded and unblinded records in the Contact Activities view.
  - Siebel Clinical administrators are assigned the `Unblinded Activity Responsibility` by default.
  - To associate other user roles with the `Unblinded Activity Responsibility`, see *Setting Access to Unblinded Activities in Core Activities View and Contact Activities View*

Inheritance Hierarchy for Blinded and Unblinded Users

This topic describes the inheritance hierarchy for blinded and unblinded users.

Sites, Regions, and Protocols are never blinded or unblinded in Siebel Clinical. It is the users at the different (site, region, or protocol) levels that are either blinded or unblinded. For example, if a user is blinded at site and protocol level but unblinded at the region level, then that user will automatically have blinded access for all site level work like site visits and activities. However, rolling up or down the configuration will change the type of user access accordingly - see the following tables for more information.

Precedence is given to configuration of the Unblinded field for users at site level. If the Unblinded field for a user is updated at site level, then position roll down from protocol and/or region cannot override the Unblinded field definition at site level, since site has more precedence.

Position Rollup

The position roll up hierarchy goes from Site, to Region, and then to Protocol level.

- When you click Position Rollup at site level, all changes (in the Unblinded field for users at site level) will be rolled up to the region and protocol levels.
- When you click Position Rollup at region level, all changes (in the Unblinded field for users at region level) will be rolled up to the protocol level.

The following table shows a user's Unblinded field value after performing a Position Rollup.

Level	User's Unblinded Field Value	Position Rollup?	Unblinded Field Value After Position Rollup
Site	Blinded	Yes, to Region and Protocol levels.	Not Applicable
Region	Unblinded	Yes, to Protocol level.	Blinded
Protocol	Blinded	Not Applicable.	Unblinded if Position Rollup is performed from region level, otherwise Blinded.

Position Rolldown

The position roll down hierarchy goes from Protocol, to Region, and then to Site level.

- When you click Position Rolldown at protocol level, all changes will be rolled down to all the regions and sites for the protocol.
- When you click Position Rolldown at region level, all changes will be rolled down to all the sites for the region.

The following table shows a user's Unblinded field value after performing a Position Rolldown.

Level	User's Unblinded Field Value	Position Rolldown?	Unblinded Field Value After Position Rolldown
Protocol	Blinded	Yes, to Region and Site levels for the selected protocol.	Not Applicable
Region	Unblinded	Yes, to Site level for the selected region.	Blinded

Level	User's Unblinded Field Value	Position Rolldown?	Unblinded Field Value After Position Rolldown
Site	Blinded	Not Applicable.	Blinded **Note:** If Position Rolldown is performed at Region level, it does not apply since precedence is always given to the value at site level.

Blinded and Unblinded Support in Siebel Mobile Disconnected Applications

In Siebel Mobile disconnected applications:

- Blinded users can view and access blinded site visits.
- Unblinded site visits are not available.
- Unblinded users can view blinded records in read-only mode irrespective of the protocol level setting **`Hide blinded content for unblinded users.`**

Blinded and Unblinded Customization Support

You can add new custom child applets under Site and Site visits and, if required, enable the blinding or unblinding functionality for those applets as follows:

- For the business component in question, create a new Enable Unblinding user property with the value Y.
- If your business component is based on the Event Activity table, then use the CSSBCClinicalGenericActivity class for your business component. Otherwise use the CSSBCClinicalGenericBusComp class for your business component.
- List Applet must use the following class: CSSSWEClinicalListBase.
- Form Applet must use the following class: CSSSWEClinicalFormBase.
- The Business Component field must contain the following field defined on column: UNBLINDED_FLG.

14 Setting Up and Configuring Clinical Data Capture and Query Management System Integration

Setting Up and Configuring Clinical Data Capture and Query Management System Integration

This chapter covers setting up and configuring Siebel Clinical Trial Management System for integration with a clinical data capture and query management system, such as Oracle Health Sciences InForm. It includes the following topics:

Overview of Clinical Data Capture and Query Management System Integration

You can use integration Web services for integrating Oracle's Siebel Clinical Trial Management System with clinical data capture and query management systems. Oracle's Siebel Clinical Trial Management System is certified for integration with Oracle Health Sciences InForm. For more information about the integration with Oracle Health Sciences InForm, see *Oracle Health Sciences InForm Publisher On Demand 2.1 Integration Guide* .

You can customize the Web services for integration with any third-party clinical application or for specific business requirements. For more information about customizing Siebel Web services, see *Siebel CRM Web Services Reference* .

The following integration processes facilitate clinical data capture integration:

- **Study subject integration.** A Siebel Clinical Web service creates screening and enrollment subjects, and enables screening and enrolling against the active subject visit template. Web services create subjects in Siebel Clinical when screening or enrollment data is entered in Oracle Health Sciences InForm.
- **Activity completion data integration.** The integration Web services update the completion dates of visits and activities in the subject visit template. The Siebel Clinical visit and activity completion data is updated using changes to the patient data that is entered in Oracle Health Sciences InForm.

Process of Setting Up Clinical Data Capture and Query Management System Integration

To set up clinical data capture and query management system integration for Siebel Clinical, perform the following tasks:

- *Activating Workflows for Clinical Data Capture and Query Management System Integration*
- *Configuring Web Services for Clinical Data Capture and Query Management System Integration*

Activating Workflows for Clinical Data Capture and Query Management System Integration

This task describes how to activate the workflows that are required for clinical data capture and query management system integration. You can use Siebel Business Process Designer to modify the workflows to suit your own business model. For more information, see *Siebel Business Process Framework: Workflow Guide* .

This task is a step in *Process of Setting Up Clinical Data Capture and Query Management System Integration*.

To activate workflows for clinical data capture and query management system integration

1. Navigate to the Administration - Business Process screen, then the Workflow Deployment view.
2. Query for and activate each of the following workflows:
    - SWI LS Clinical Subject Inbound - Subject
    - SWI LS Clinical Subject Inbound - Activity
    - SWI - Protocol Number Lookup
    - LS Clinical - DeleteNonAppVisits Process
3. Verify that each activated workflow is added to the Active Workflow Processes view at the end of the screen.

Configuring Web Services for Clinical Data Capture and Query Management System Integration

This task describes how to configure the Web services that are required for clinical data capture and query management system integration. For more information about configuring Web services, see *Integration Platform Technologies: Siebel Enterprise Application Integration* .

> **Note:** It is recommended that you use HTTPS authentication. For information about configuring Secure Sockets Layer (SSL) for HTTPS authentication, see *Siebel Security Guide* .

This task is a step in *Process of Setting Up Clinical Data Capture and Query Management System Integration*.

To configure Web services for clinical data capture and query management system integration

1. Navigate to the Administration - Web Services screen, then the Inbound Web Services view.
2. Query for each of the following Web services, and update the language and address variables:
    - ClinicalSubject Inbound Web service.
    - LS Clinical Protocol Site Interface Service
3. Click Clear Cache on the Inbound Web Services applet.

Configuring Protocol Integration Fields for Oracle Health Sciences InForm Integration

The CDMS Study ID field in Siebel Clinical maps a protocol in Siebel Clinical to a clinical trial in Oracle Health Sciences InForm. Multiple protocols can be associated with a clinical program in Siebel Clinical. When you create a protocol record, you can also add extra information about the protocol, such as financial information, central laboratory information, and so on.

To configure protocol integration fields for Oracle Health Sciences InForm integration

1. Navigate to the Administration - Clinical screen, then the Protocol List view.
2. In the Protocol list, query for the correct protocol.
3. Drill down on the protocol number field.
4. Navigate to the integration section of the More Info view.
5. Complete the integration fields as shown in the following table.

Field	Comments
CDMS Study ID	Type the ID of the CDMS study. This required field links a clinical protocol in Siebel Clinical to a clinical study in an external application. For integration with Oracle Health Sciences InForm, set the value to the trial name in Oracle Health Sciences InForm.
Synchronize Active Study Sites	This field is not applicable for InForm integration.
Safety Study ID	This field is not applicable for InForm integration.
Plan Study ID	This field is not applicable for InForm integration.

Integrating Data for Subject Visits with Data for Activities

Subject visit templates allow you to set up a template schedule. The template schedule is based on the protocol document. You use the template schedule to generate screening, rescreening, and enrollment schedules for each subject, according to the subject's screening, rescreening, and enrollment dates.

The Clinical Item Integration field in the subject visit template is used for integrating visit data with activity data between Siebel Clinical and Oracle Health Sciences InForm.

To integrate data for subject visits with data for activities

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.
2. In the Subject Visit Templates list, create a new record and complete the necessary fields.

   The Clinical Item fields in the Visits and Activities applets are automatically populated.
3. Verify that the Clinical Item fields in the Visits and Activities applets are populated as specified in the following table.

Field	Comments
Visits - Clinical Item	When you create a visit, the clinical item in the Visits applet is populated with the name of the visit. The clinical item value defines the completion criteria for the visit in Oracle Health Sciences InForm. If multiple versions of the subject visit template exist, and some visits are the same in both template versions, then you can specify the same clinical item value. This feature allows both visits to have the same completion criteria in Oracle Health Sciences InForm. **Note:** The clinical item value for a visit must be unique within a version of a subject visit template.
Activities - Clinical Item	When you create a visit activity, the clinical item in the Activities applet is populated with the value in the Activities Description field. The clinical item value defines the completion criteria for the activity in Oracle Health Sciences InForm. The user often completes the same activity at multiple visits, therefore the user can assign the same clinical item value to each activity, and then define the completion criteria only once in Oracle Health Sciences InForm. **Note:** The clinical item value for an activity must be unique within a visit in a version of a subject visit template.

About Exporting Data for Sites

Use the LS Clinical Protocol Site Interface Service Web service to export the data in the Protocol Site List view from Siebel Clinical Trial Management System to an external application. For information about the Protocol Site List view, see *Creating Sites for Clinical Trials*.

The following data is exported:

- Account
- Initiation completed date
- Primary investigator
- Protocol number
- Region
- Site number
- Status

About Integrating Data for Activity Completion

Oracle Health Sciences InForm controls the integration of activity completion data between Siebel Clinical and Oracle Health Sciences InForm. In Oracle Health Sciences InForm, when patient data is entered that complies with the criteria for the clinical item value for a visit or activity, Siebel Clinical receives a message containing a completion date. The visit or activity is updated with the status of Complete, and the completion date is populated.

If the message from Oracle Health Sciences InForm does not contain a completion date, and the visit or activity in Siebel Clinical already has a status of Complete, then no change is made to the completion date or status in Siebel Clinical.

Oracle Health Sciences InForm integrates activity completion data with Siebel Clinical as follows:

- Siebel Clinical searches for the subject using the unique subject identifier (row ID). When the subject is found, it searches for the activity as follows:
    - Siebel Clinical searches for the activity using the clinical item for the visit and the clinical item for the visit activity as follows:
        - If the clinical item in the update corresponds to a subject visit, then the completed date for that visit is updated.
        - If the clinical item in the update corresponds to an activity for a subject visit, then the completed date for that activity is updated.
    - If the clinical item sent from Oracle Health Sciences InForm cannot be mapped to an activity completion item in Siebel Clinical, then an error is generated to indicate that the update failed.

15 Setting Up and Configuring Clinical Data Management System Integration

Setting Up and Configuring Clinical Data Management System Integration

This chapter covers setting up and configuring Siebel Clinical for integration with a clinical data management system. It includes the following topics:

Overview of Clinical Data Management System Integration

The following integration processes facilitate clinical trial integration:

- **Study subject integration.** A Siebel Clinical Web service creates screening and enrollment subjects, and enables screening and enrolling against the active subject visit template. A integration exists for Siebel Clinical and Oracle Health Sciences InForm that uses this Web service to create subjects in Siebel Clinical when screening or enrollment data is entered in Oracle Health Sciences InForm.
- **Activity completion data integration.** The integration for Siebel Clinical and Oracle Health Sciences InForm uses a Siebel Clinical Web service to update the completion dates of visits and activities in the subject visit template. The customer configures trigger conditions in the Oracle Health Sciences InForm trial to send the completion date from Oracle Health Sciences InForm to Siebel.

The integration from Oracle Health Sciences InForm to Siebel Clinical automates the creation of subjects in Siebel Clinical and the completion of visits and activities.

The automation of these processes enables the timely and accurate payments to investigators. It also provides a means to more accurately track and respond to issues relating to site performance and protocol adherence.

For information about configuring Oracle Health Sciences InForm for integration with Siebel Clinical Trial Management System, see *Oracle Health Sciences InForm Publisher On Demand 2.1 Integration Guide* .

About Customizing Web Services for Clinical Data Management System Integration

You can customize the ClinicalSubject Inbound Web service for integration with any third-party clinical study application or for specific business requirements. For more information about customizing Siebel Web services, see *Siebel CRM Web Services Reference* .

Process of Setting Up Clinical Data Management System Integration

To set up clinical data management system integration for Siebel Clinical, perform the following tasks:

- *Activating Workflows for Clinical Data Management System Integration*
- *Configuring Web Services for Clinical Data Management System Integration*

Activating Workflows for Clinical Data Management System Integration

This task describes how to activate the workflows that are required for clinical data management system integration. You can use Siebel Business Process Designer to modify the workflows to suit your own business model. For more information, see *Siebel Business Process Framework: Workflow Guide* .

This task is a step in *Process of Setting Up Clinical Data Management System Integration*.

To activate workflows for clinical data management system integration

1. Navigate to the Administration - Business Process screen, then the Workflow Deployment view.
2. Query for and activate each of the following workflows:
    - SWI LS Clinical Subject Inbound - Subject
    - SWI LS Clinical Subject Inbound - Activity
    - SWI - Protocol Number Lookup
    - LS Clinical - DeleteNonAppVisits Process
3. Verify that each activated workflow is added to the Active Workflow Processes view at the end of the screen.

Configuring Web Services for Clinical Data Management System Integration

This task describes how to configure the Web services that are required for clinical data management system integration. For more information about configuring Web services, see *Integration Platform Technologies: Siebel Enterprise Application Integration* .

> **Note:** It is recommended that you use HTTPS authentication. For information about configuring Secure Sockets Layer (SSL) for HTTPS authentication, see *Siebel Security Guide* .

This task is a step in *Process of Setting Up Clinical Data Management System Integration*.

To configure Web services for clinical data management system integration

1. Navigate to the Administration - Web Services screen, then the Inbound Web Services view.
2. Query for each of the following Web services, and update the language and address variables:
   - ClinicalSubject Inbound Web service.
   - LS Clinical Protocol Site Interface Service
3. Click Clear Cache on the Inbound Web Services applet.

Integrating Data for Subject Visits with Data for Activities

Subject visit templates allow you to set up a template schedule. The template schedule is based on the protocol document. You use the template schedule to generate screening, rescreening, and enrollment schedules for each subject, according to the subject's screening, rescreening, and enrollment dates.

The Clinical Item Integration field in the subject visit template is used for integrating visit data with activity data between Siebel Clinical and Oracle Health Sciences InForm.

To integrate data for subject visits with data for activities

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.
2. In the Subject Visit Templates list, create a new record and complete the necessary fields.

   The Clinical Item fields in the Visits and Activities applets are automatically populated.
3. Verify that the Clinical Item fields in the Visits and Activities applets are populated as specified in the following table.

Field	Comments
Visits - Clinical Item	When you create a visit, the clinical item in the Visits applet is populated with the name of the visit. The clinical item value is passed from Oracle Health Sciences InForm to Siebel Clinical when updating the visit or activity completion date. If multiple versions of the subject visit template exist, and some visits are the same in both template versions, then you can specify the same clinical item value. This feature allows both visits to have the same completion criteria in Oracle Health Sciences InForm. **Note:** The clinical item value for a visit must be unique within a version of a subject visit template.
Activities - Clinical Item	When you create a visit activity, the clinical item in the Activities applet is populated with the value in the Activities Description field. The clinical item value for the activity is passed from Oracle Health Sciences InForm when sending the completion date for the activity. **Note:** The clinical item value for an activity must be unique within a visit in a version of a subject visit template.

About Integrating Data for Clinical Subjects

The customer defines events that invoke the Siebel Web service to create and update subject information. The event defines what data entry in Oracle Health Sciences InForm will cause Oracle Health Sciences InForm to call the Siebel Web service. When patients are assigned to patient positions in Oracle Health Sciences InForm, or patient data is entered for a patient position, the integration triggers the creation of a subject in Siebel Clinical. Updates to the information for the patient in Oracle Health Sciences InForm are exported to Siebel Clinical. Deleted data in Oracle Health Sciences InForm is not reflected in Siebel Clinical. Patient data for Oracle Health Sciences InForm and subject data for Siebel Clinical is integrated as follows:

- **Subject Messages.** When a subject message is received by Siebel Clinical from Oracle Health Sciences InForm, Siebel Clinical evaluates it to determine if a new subject must be created or if an existing subject must be updated. Siebel Clinical searches for the system ID of the subject. If the system ID does not exist, then Siebel Clinical creates a new subject. If it does exist, then Siebel Clinical updates the subject.
- **Subject Number and Subject ID.** Oracle Health Sciences InForm sends the subject number over as a Subject ID to Siebel Clinical.
- **Encounter Date.** The customer decides which date from Oracle Health Sciences InForm to map to Encounter Date in Siebel Clinical, and configures the mapping accordingly.
- **Screen Date.** The customer decides which date from Oracle Health Sciences InForm to map to Screen Date in Siebel Clinical, and configures the mapping accordingly.

- **Informed Consent Date.** Informed Consent Date is required only if a new Subject Visit Template is being applied. If Siebel Clinical does not have an informed consent date, then an Effective Date (for the Subject View Template) is sent instead of an informed consent date.

About Integrating Data for Activity Completion

Oracle Health Sciences InForm controls the integration of activity completion data between Siebel Clinical and Oracle Health Sciences InForm. The customer defines in the Oracle Health Sciences InForm trial what data must be collected to determine that a visit or activity in Siebel Clinical is complete. When those conditions are met, Siebel Clinical receives a message. The visit or activity is updated with the status of Complete, and the completion date is populated.

If the message from Oracle Health Sciences InForm does not contain a completion date, and the visit or activity in Siebel Clinical already has a status of Complete, then no change is made to the completion date or status in Siebel Clinical.

Oracle Health Sciences InForm and Siebel Clinical integrate activity completion data as follows:

- Siebel Clinical searches for the subject using the unique subject identifier (row ID). When the subject is found, it searches for the activity as follows:
    - Siebel Clinical searches for the activity using the clinical item for the visit and the clinical item for the visit activity as follows:
        - If the clinical item in the update corresponds to a subject visit, then the completed date for that visit is updated.
        - If the clinical item in the update corresponds to an activity for a subject visit, then the completed date for that activity is updated.
    - If the clinical item sent from Oracle Health Sciences InForm cannot be mapped to an activity completion item in Siebel Clinical, then an error is generated to indicate that the update failed.

16 Setting Up and Using the Siebel Mobile Disconnected Application for Siebel Clinical

Setting Up and Using the Siebel Mobile Disconnected Application for Siebel Clinical

This chapter covers setting up a Siebel Mobile disconnected application for Siebel Clinical and describes the tasks that a user of the application can execute in online (connected) and offline (disconnected) mode. It includes the following topics:

- *About Siebel Mobile Disconnected Applications*
- *About the Siebel Mobile Disconnected Application for Siebel Clinical*
- *Configuring a Siebel Mobile Disconnected Application for Siebel Clinical*
- *Using the Siebel Mobile Disconnected Application for Siebel Clinical*
- *Managing My Site Visits for Siebel Clinical*
- *Managing My Sites for Siebel Clinical*

About Siebel Mobile Disconnected Applications

Siebel Mobile applications allow you to access Siebel CRM information with your mobile device in real time by permitting you to access a browser-based version of the application (such as Siebel Clinical) on your mobile device (android or iOS tablet or smartphone).

Siebel Mobile Disconnected Applications are Siebel applications (such as Siebel Clinical) accessed from a browser on a mobile device (android or iOS tablet or smartphone), which synchronizes data directly to the browser client without use of additional software or a network connection.

About the Siebel Mobile Disconnected Application for Siebel Clinical

Clinical Research Associates (CRAs) often work at clinical sites with limited or no internet facility. An ability to use Siebel Clinical in offline mode helps CRAs to capture real time data related to site visits such as monitoring trip reports, site accounts and contacts, and site findings.

Using the current version of the Siebel Mobile disconnected application for Siebel Clinical, you can:

- Perform a monitoring trip report in online (connected) and offline (disconnected) mode.
- Manage My Site Visits and My Sites for Siebel Clinical.

Note that Site Visit and Trip Report are separate entities. You can complete a clinical trip report by changing the Visit Status field to Done in offline mode. The Trip Report status field can only be changed in online mode.

- Enter data in offline mode and later synchronize the data with the Siebel Clinical application over the internet.

Before starting to use the current version of the Siebel Mobile disconnected application for Siebel Clinical, you must do the following:

- Synchronize data in the Siebel Mobile disconnected application for Siebel Clinical in online mode first, before going offline, so that all existing trip report data is loaded and will be available in offline mode.
- Create site visits using the Siebel Clinical Web application in online mode (for more information see, *Creating and Managing Site Visits*).

You perform data synchronization to the Siebel Clinical application in online mode.

Configuring a Siebel Mobile Disconnected Application for Siebel Clinical

Use the following procedure to configure a Siebel Mobile disconnected application for Siebel Clinical.

To configure a Siebel Mobile disconnected application for Siebel Clinical

1. Log in to the Siebel Clinical application as administrator.
2. Navigate to the Administration - Server Configuration screen, then the Enterprises, Component Definitions view and do the following:
   a. Query for the Mobile Data Extraction (ENU) component, make a copy of the record, and then set the following record values:

Field	Value
Component	eClinical Mobile Data Extraction (ENU)
Alias	eClinicalMobileDbXtract_enu
Component Group	Disconnected Mobile Synchronization
Description	eClinical Mobile Data Extraction

   b. Select the eClinicalMobileDbXtract_enu component and set the following parameters for the component:

Name	Value
Application Name	Siebel eClinical Mobile

Name	Value
Language Code	ENU
OM - Configuration File	eclinicalm.cfg
Application Splashtext	Siebel Clinical Mobile
Application Title	Siebel Clinical Mobile

c. Click Activate to activate the new eClinical Mobile Data Extraction (ENU) component.
d. Click Synchronize to synchronize the eClinical Mobile Data Extraction (ENU) component

3. Navigate to the Synchronize view, and click Synchronize.
4. Navigate to the Component Groups view, and do the following:
   a. Select the eClinicalMObjMgr_enu component and set the following parameters for the component:

Name	Value
EnableInlineForList	Never
EnableOfflineMode	True

   b. Query for each of the following component groups:
      HandheldSync
      HandheldSyncSIS
      Siebel Remote
      MobileSync
   c. For each of these component groups:
      - Select the component group and then click Enable.
      - In the Component Group Assignments applet, click Enable.
5. Restart Siebel Services and Siebel Gateway.
6. Navigate to the Administration - Server Management screen, then the Jobs view and do the following:
   a. Create a new job with the parameter values shown in the following table:

Field	Value
Component Group	Database Extract

Field	Value
Job Parameter	Name: Client Name
Job Parameter	Value: <USER ID>-MOBILE

b. Submit the job.
The status of the job changes to Success when the database extraction job is successful.

Using the Siebel Mobile Disconnected Application for Siebel Clinical

The tasks that a user of the Siebel Mobile application for Siebel Clinical can execute in online and offline mode include the following:

- *Getting Started with Siebel Mobile Disconnected Applications* (general tasks)
- *Switching to Offline Mode and Synchronizing Data*
- *Managing My Site Visits for Siebel Clinical*
- *Managing My Sites for Siebel Clinical*

Note: You must complete the relevant setup tasks detailed in this guide before using the Siebel Mobile disconnected application for Siebel Clinical.

Getting Started with Siebel Mobile Disconnected Applications

For information about how to get started with Siebel Mobile disconnected applications and about the common procedures that you can execute in online (connected) and offline (disconnected) mode in all applications, see the Getting Started chapter in *Siebel Mobile Guide: Disconnected* which includes information about the following:

- Logging in to and out of Siebel Mobile
- Navigating the Siebel Mobile user interface
- Managing records in Siebel Mobile
- Reviewing notification messages in Siebel Mobile
- Configuring application settings for Siebel Mobile
- Displaying location details in Siebel Mobile
- Running predefined queries in Siebel Mobile
- Using Attachments in Siebel Mobile
- Printing from Siebel Mobile
- Process of using Siebel Mobile disconnected applications in offline mode

Switching to Offline Mode and Synchronizing Data

You can use the Siebel Mobile disconnected application for Siebel Clinical in offline mode. In offline mode, your mobile device is not connected to the Siebel Server and you cannot synchronize any changes that you make while working in offline mode. You must switch back to online mode, and then synchronize the changes.

A prerequisite to using the Siebel Mobile disconnected application for Siebel Clinical in offline mode is that you create sites and site visits in the Siebel Clinical Web application first (see *Creating and Managing Site Visits*).

When you initially log in to the Siebel Mobile disconnected application for Siebel Clinical, you are in online mode. You must then decide whether to continue working in online (connected) mode or to switch to offline (disconnected) mode. If you decide to stay working in online mode, then no further steps are required for data synchronization. If you decide to work in offline mode, then you must switch to offline mode. Then when you are finished working in offline mode, you must synchronize the data or upload the changes you made while working in offline mode to the Siebel Server.

To switch to offline mode and synchronize data

1. Log in to the Siebel Mobile disconnected application for Siebel Clinical.
2. Tap Go Offline (the solid airplane icon) on the application banner to go offline and work in disconnected mode.

   If this is your fist time going offline, then you must wait for the following two notification messages appear:

   a. Data extraction has been scheduled.

      This message may take a while to appear.
   b. Data is ready for download.

      After you receive this message, you can start working in offline mode.

      The following notification appears whenever new data is created in online mode: New data is ready for download.
3. When finished working in offline mode, tap Go Online (the empty airplane icon) on the application banner to synchronize the data changes and select one of the following as required:

   - **Upload and Go Online.** Tap to trigger a data upload and go online.
   - **Sync and stay Offline.** Tap to synchronize the data changes but remain offline.
   - **Upload Only and stay Offline.** Tap to trigger a data upload but remain offline.

Managing My Site Visits for Siebel Clinical

To ensure the smooth operation of clinical trials, CRAs (clinical research associates) typically carry out different types of visits to sites, such as, pre-study visits, invitation visits, monitoring visits, and close-out visits.

The following procedures related to site visit management are included in this topic:

- *Displaying My Site Visits Information*
- *Modifying My Site Visits Information*

- *Modifying Checklist Activity Information*
- *Modifying Current Follow Up Information*
- *Modifying All Follow Up Information*
- *Modifying CRF Tracking Information*

For more information about creating site visits, see *Creating and Managing Site Visits*creating.

Displaying My Site Visits Information

CRAs or logged in users can view all available site visits and related information in the My Site Visits screen.

To display My Site Visits information

1. Tap Side Menu on the application banner, and then tap My Site Visits to display the following:
    - The My Site Visits list in the side pane, which includes the following information: Visit Name, Visit Start, Account (associated with the visit).

      Use these fields to search for a particular site visit.
    - The site visit details in the main pane, which includes the following information: Visit Status (Editable), Visit Type, Primary Assignee, Trip report Status, Site, Region, Completed (Editable), Comments (Editable).

      And the following related information: Checklist Activities, Current Follow Up, All Follow Up, CRF Tracking.
2. Tap a record in the My Site Visits list.

   All the site visit details for the selected record appear, including the following related information:
    - **Checklist Activities.** Tap the down arrow next to Checklist Activities to view all the checklist activities associated with the selected site visit.
    - **Current Follow Up.** Tap the down arrow next to Current Follow Up to view the most current follow up information associated with the selected site visit.
    - **All Follow Up.** Tap the down arrow next to All Follow Up to view all the follow up information associated with the selected site visit.
    - **CRF Tracking.** Tap the down arrow next to CRF Tracking to view all the CRF tracking information associated with the selected site visit.

Modifying My Site Visits Information

Complete the following procedure to modify My Site Visits information.

To modify My Sites Visits information

1. Tap Side Menu on the application banner, and then tap My Site Visits to display the following:
    - The My Site Visits list in the side pane.
    - The site visit details in the main pane.
2. Update an existing site visit as follows:

a. Tap a record in the My Site Visits list.
   All the site visit details for the selected record appear.
b. Update the following fields as required: Visit Status, Completed, Comments.
c. To modify checklist activity information, see *Modifying Checklist Activity Information*.
d. To modify current follow up information, see *Modifying Current Follow Up Information*.
e. To modify all follow up information, see *Modifying All Follow Up Information*.
f. To modify CRF tracking information, see *Modifying CRF Tracking Information*.

Modifying Checklist Activity Information

Complete the following procedure to modify the checklist activity for a site visits.

To modify checklist activity information

1. Tap Side Menu on the application banner, and then tap My Site Visits to display the following:
   - The My Site Visits list in the side pane.
   - The site visit details in the main pane.
2. Tap a record in the My Site Visits list.
   All the site visit details for the selected record appear.
3. Update the checklist activity information as follows:
   a. Tap the down arrow next to Checklist Activities and then select the record that you want to modify.
   b. Update the following fields as required: Quantity, UOM, Response, Comments.
4. Add a new checklist activity as follows:
   a. Tap New (the plus (+) icon) next to Checklist Activity.
   b. Enter the information for the checklist activity in the fields that appear and then save the record.

Modifying Current Follow Up Information

Complete the following procedure to modify the current follow up information for a site visit.

To modify current follow up information

1. Tap Side Menu on the application banner, and then tap My Site Visits to display the following:
   - The My Site Visits list in the side pane.
   - The site visit details in the main pane.
2. Tap a record in the My Site Visits list.
   All the site visit details for the selected record appear.
3. Update the current follow up information as follows:
   a. Tap the down arrow next to Current Follow Up and then select the record that you want to modify.

b. Update the following fields as required: Activity Type, Description, Due, Status, Comments.

4. Add a new follow up activity as follows:

   a. Tap New (the plus (+) icon) next to Current Follow Up.
   b. Enter the information for the follow up activity in the fields that appear and then save the record.

Modifying All Follow Up Information

Complete the following procedure to modify all follow up information for a site visit.

To modify all follow up information

1. Tap Side Menu on the application banner, and then tap My Site Visits to display the following:
   - The My Site Visits list in the side pane.
   - The site visit details in the main pane.
2. Tap a record in the My Site Visits list.

   All the site visit details for the selected record appear.
3. Update all follow up information as follows:

   a. Tap the down arrow next to All Follow Up and then select the record that you want to modify.
   b. Update the following fields as required: Activity Type, Description, Due, Status, Completed Date, Comments.

Modifying CRF Tracking Information

Complete the following procedure to modify the CRF tracking information for a site visit.

To modify CRF tracking information

1. Tap Side Menu on the application banner, and then tap My Site Visits to display the following:
   - The My Site Visits list in the side pane.
   - The site visit details in the main pane.
2. Tap a record in the My Site Visits list.

   All the site visit details for the selected record appear.
3. Update the CRF tracking information as follows:

   a. Tap the down arrow next to CRF Tracking and then select the record that you want to modify.
   b. Tap Attach-CRF to make all the fields in the selected record editable, and then update the fields as required.
4. Delete CRF tracking information as follows:

   a. Select the record that you want to modify.
   b. Tap Detach-CRF.

Doing this makes all the fields in the selected record read-only and then deletes all data entered for that record (if any).

Managing My Sites for Siebel Clinical

A *site* is an account that a principal investigator manages for a particular protocol.

The following procedures related to site management are included in this topic:

- *Displaying My Sites Information*
- *Viewing Site Contacts Information*
- *Viewing Site Visits Information*

For more information about creating sites for clinical trials, see *Process of Managing Sites and Contacts for Clinical Trials*.

Displaying My Sites Information

CRAs or logged in users can view all available sites, site details and related information in the My Sites screen.

To display My Sites information

1. Tap Side Menu on the application banner, and then tap My Sites to display the following:
    - The My Sites list in the side pane, which includes the following information: Protocol #, Protocol Name, Account.

      Use these fields to search for a particular site.

      Sites with a status of Terminated do not appear in the My Sites list.
    - The site details in the main pane, which includes the following information: Site #, Parent Site (available for satellite sites only), Site Initiated (date), Status.

      And the following related information: Site Contacts, Site Visits.
2. Tap a record in the My Sites list.

   All the site details for the selected record appear, including the following related information:
    - **Site Contacts.** For more information, see *Viewing Site Contacts Information*.
    - **Site Visits.** For more information, see *Viewing Site Visits Information*.

Viewing Site Contacts Information

Complete the following procedure to view the contacts associated with a site.

To view site contact information

1. Tap Side Menu on the application banner, and then tap My Sites to display the following:
    - The My Sites list in the side pane.
    - The site details in the main pane.
2. Tap a record in the My Sites list.

   All the site details for the selected record appear.
3. Tap the down arrow next to Site Contacts.

   All the contacts associated with the selected site appear.

Viewing Site Visits Information

Complete the following procedure to view the visits associated with a site.

To view site visit information

1. Tap Side Menu on the application banner, and then tap My Site Visits to display the following:
    - The My Sites list in the side pane.
    - The site details in the main pane.
2. Tap a record in the My Sites list.

   All the site details for the selected record appear.
3. Tap the down arrow next to Site Visits.

   All the visits associated with the selected site appear.

17 Setting Up Integration Between CTMS and eTMF

Setting Up Integration Between CTMS and eTMF

This chapter describes how to integrate CTMS with an electronic trial master file (eTMF) system. It includes the following topics:

- *Overview of Integration Between CTMS and eTMF*
- *CTMS and eTMF Integration Process Flow*
- *Process of Setting Up Integration Between CTMS and eTMF*
- *Enabling Integration Between CTMS and eTMF*
- *Configuring Email Recipients*
- *Configuring the LS Clinical Trip Report File Transfer Web Service*
- *Manually Generating Trip Report Files*

Note: The feature described in this chapter is available in Siebel CRM 18.9 Update and later releases.

Overview of Integration Between CTMS and eTMF

An electronic trial master file (eTMF) is a content management system for the pharmaceutical industry, providing a formalized means of organizing and storing documents, images, and other digital content for clinical trials that may be required for compliance with government regulatory agencies.

CRAs typically create 2-3 trip reports per week, per customer. After site visit approval, any approved trip reports are then moved from CTMS to an eTMF system. With the introduction of this new feature (CTMS integration with eTMF), the approved trip reports can automatically be sent from CTMS to eTMF. This avoids the inefficiency of having to manually move the trip reports.

To facilitate the automatic movement of approved trip report files from CTMS to an eTMF system, CTMS provides the LS Clinical Trip Report File Transfer Web service (an inbound SOAP Web service), which is used as follows:

- The eTMF system calls the LS Clinical Trip Report File Transfer Web service to pull the trip report file into the eTMF system.

  The eTMF system can pull one or more trip report files from CTMS and can schedule this to happen periodically. You can configure any combination of the following parameters to pull trip report files: Trip report ID, Visit Name, Visit Type, Visit Start, Protocol, Site, Region, Principal Investigator, Approved Date.
- The eTMF system uses the same LS Clinical Trip Report File Transfer Web service to send or return the trip report file *received date* and *URL link* (to where the trip report file is stored) from eTMF back to CTMS.
- CTMS uses the trip report file *URL link* to open and review the trip report file as required.

CTMS and eTMF Integration Process Flow

The overall process flow involved in the integration between CTMS and eTMF is as follows:

1. After a site visit is approved, a trip report file is automatically generated with a status of Approved.

   For this initial step to happen, integration must be enabled between CTMS and eTMF as shown in *Enabling Integration Between CTMS and eTMF*.

   If for some reason, a trip report file is not generated automatically once a site visit is approved, then an email is sent to the concerned CRA notifying them of the situation. In this instance, the CRA must contact their administrator to see if this is due to a network or other issue and once confirmed, the CRA can manually generate the trip report file by clicking Generate Report. For more information, see *Manually Generating Trip Report Files*.
2. The approved trip report file is automatically added to the Site Visit Attachment view and an email is sent to the key CRA and eTMF recipients notifying them that an approved trip report file is ready to be sent to eTMF.

   You set up the email recipients as shown in *Configuring Email Recipients*.
3. The approved trip report file is then pulled from CTMS into eTMF using the LS Clinical Trip Report File Transfer Web service.

   For information on setting up this Web service, see *Configuring the LS Clinical Trip Report File Transfer Web Service*.
4. eTMF uses the same LS Clinical Trip Report File Transfer Web service to return the following information to CTMS:

   - **Received date.** The date the trip report file was received by eTMF.
   - **URL link.** The URL link to the trip report file in eTMF.

   CTMS stores this returned information in the Site Visit Attachment view of that trip report.

   New versions of a trip report, once approved, are sent to eTMF in the same way.

Process of Setting Up Integration Between CTMS and eTMF

To set up integration between CTMS and eTMF, perform the following tasks:

1. *Enabling Integration Between CTMS and eTMF*

   Integrating Siebel Clinical with Oracle Business Intelligence Publisher (BI Publisher) to generate reports is a prerequisite to this step.
2. *Configuring Email Recipients*
3. *Configuring the LS Clinical Trip Report File Transfer Web Service*
4. (Optional) *Manually Generating Trip Report Files*

Enabling Integration Between CTMS and eTMF

CTMS integration with eTMF is disabled by default in Siebel Clinical. The following procedure shows how to enable CTMS integration with eTMF so that trip report files, upon site visit approval, will automatically be sent from CTMS to eTMF.

This task is a step in *Process of Setting Up Integration Between CTMS and eTMF*.

Note: Siebel Clinical must be integrated with Oracle Business Intelligence Publisher (BI Publisher) to generate reports.

To enable CTMS integration with eTMF

1. Navigate to the Administration - Application screen, then the System Preferences view.
2. Set CL - Generate TripReport to Y to enable trip report generation after approval.
3. (Optional) The following business component calculated fields can be configured:

BC Name	Field	Field
Clinical Trip Report	TR File Name	TR File Type

The default file naming convention for the trip report file is as follows:

- TR File Name: `Trip Report_<Id>_<site visit date>_<account>`
- TR File Type: `PDF`

Configuring Email Recipients

When an approved trip report file is automatically added to the Site Visit Attachment view, an email is sent to key CRA and eTMF recipients notifying them that an approved trip report file is ready to send to the eTMF system. The following procedure shows you how to configure the email recipients.

This task is a step in *Process of Setting Up Integration Between CTMS and eTMF*.

To configure email recipients

1. Navigate to the Administration - Application screen, then the System Preferences view.
2. Configure the system preferences as shown in the following table.

System Preference Name	Value	Description
CL - TripReport Email Template	Trip Report Email Template	The trip report email template to use to send an email to the recipients defined in the CL - TripReport

System Preference Name	Value	Description
		Email To List system preference (notifying them that an approved trip report file is ready to send to eTMF). The Trip Report Email Template is available and configured by default and, if required, customers can modify the template.
CL - TripReport Email Profile	`<Trip Report Email Profile>`	The trip report email profile to use. The following step shows how to define the email profile.
CL - TripReport Email To List	`<Recipient List>`	A semicolon-delimited list of email addresses to which an email is sent after Trip Report generation.

3. Define an email profile as follows:
   a. Navigate to the Administration Communication screen, then the Communication Drivers and Profile view.
   b. Query for Internet SMTP/POP3 Server and then create a new record, name it Trip Report Email Profile and set the parameters for the email profile as shown in the following table.

Parameter Name	Value
From Address	`SIEBEL_CTMS_ADMIN@oracle.com`
SMTP Server	`<SMTP Server VM>`
SMTP Server Port	`<SMTP Server Port>`

Configuring the LS Clinical Trip Report File Web Service

The eTMF system calls the LS Clinical Trip Report File Transfer Web service (an inbound SOAP Web service provided by CTMS) to pull the trip report file into the system and in turn send the trip report *received date* and *URL link* from eTMF back to CTMS.

To pull a specific trip report or a group of trip reports from CTMS into the eTMF system, then configure one or more of the input parameters, as listed in the following procedure, in the LS Clinical Trip Report File Transfer Web service.

This task is a step in *Process of Setting Up Integration Between CTMS and eTMF*.

To configure the LS Clinical Trip Report File Transfer Web service

1. Navigate to the Administration — Web Services screen, then the Inbound Web Services view.

2. Query for and select the LS Clinical Trip Report File Transfer Web service.
3. Configure one or more of the following input parameters in the LS Clinical Trip Report File Transfer Web service to pull a specific trip report or a group of trip reports from CTMS into the eTMF system.

> **Note:** The input parameters that you configure will act like a filter. Only trip reports that match all the criteria (configured input parameters) will be pulled. For example, if the Protocol parameter and no other parameter is set, then all trip reports for the specified protocol will be pulled.

Field	Description
Trip Report ID	The ID associated with the trip report.
Visit Name	The name of the site visit.
Visit Type	The type of site visit.
Visit Start	Starting date of the site visit.
Protocol	The protocol or study ID.
Site	The site associated with the trip report file.
Region	The geographical region to which the site belongs.
Principal Investigator	The principal investigator for the site (contact associated with the site).
Approved Date	The date the trip report was approved.

Manually Generating Trip Report Files

If for some reason a trip report file is not generated automatically once a site visit is approved (this is usually due to BI Publisher not working), then a notification is sent to the concerned team members notifying them of the situation and the Generate Report button on the Site Visits screen is activated.

You configure the team members to notify (upon failure to generate a trip report file once a site visit is approved) in the BC user property BIP Error Notification List. The values you can assign to BIP Error Notification List are Approver, Reviewer, Primary, and Team. The default value is Primary and a maximum of two values can be configured. For example: Approver, Reviewer.

This task is a step in *Process of Setting Up Integration Between CTMS and eTMF*.

To manually generate a trip report file

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. Query for the approved site visit that you want (where the trip report file failed to generate).
3. Click Generate Report.

   A trip report file is generated with a status of Approved and it is automatically added to the Site Visit Attachment view

18 Developer's Reference for Siebel Clinical

Developer's Reference for Siebel Clinical

This chapter contains information about configuring and customizing Siebel Clinical using Siebel Tools and about customizing Siebel Clinical Web services. It includes the following topics:

- *About Using the Siebel REST API with Siebel Clinical*
- *Overview of User Properties for Siebel Clinical*
- *User Properties for Business Components in Siebel Clinical*
- *User Properties for Business Services in Siebel Clinical*
- *Applet Properties in Siebel Clinical*
- *Field Properties in Siebel Clinical*
- *System Preferences in Siebel Clinical*
- *Workflows in Siebel Clinical*
- *Web Services in Siebel Clinical*

This chapter assumes that you are familiar with the processes and conventions of working with Siebel Tools to change object properties. For more information about changing properties in Siebel Tools, see *Configuring Siebel Business Applications* .

About Using the Siebel REST API with Siebel Clinical

You can use the Siebel CRM Representational State Transfer (REST) application programming interface (API) to create, synchronize, and delete Siebel Clinical users. For more information about Siebel REST API and about using Siebel REST API with Siebel Clinical, see *Siebel REST API Guide* .

You can also use the Siebel REST API to invoke business services using Siebel server script techniques. For more information, see *Using Siebel Tools* .

When you create or synchronize Siebel Clinical users, you can pass default position and responsibility information in the REST API response by configuring the LS Clinical User Provisioning Service Business method. For more information, see the topic about configuring Siebel Clinical users in *Siebel REST API Guide* .

Overview of User Properties for Siebel Clinical

User properties are object definitions that are children of an applet, business component, control, field, or list column, and configure specialized behavior beyond the configuration in the properties of the parent object definition.

User properties drive some Siebel Clinical functionalities. You can customize these functionalities through their respective user properties. With user properties, you can control the behavior of the user interface, change default settings or leave them as they are, and enable or disable functionalities.

This chapter lists user properties that are specific to Siebel Clinical. For more information about user properties and user properties that apply to all Siebel Business Applications, see *Siebel Developer's Reference* .

User Properties for Business Components in Siebel Clinical

The following table describes the business component user properties that you can use to enable and configure functionality for Siebel Clinical.

User Property	Business Component	Description
Apply Templates WorkFlow Process Name	LS Subject Schedule Date VBC	This property defines the workflow process that is invoked when the Enroll Screen Rescreen Through WorkFlow property is set to Y, and when the Disable Delete Non App Visit property is set to N. The default value is **`LS Clinical - ApplyTemplates Process`**. If the user clicks No on the pop-up message that the Disable Delete Non App Visit property enables, then LS Clinical - ApplyTemplates Process is invoked, and the subject visit template is applied.
Automatic Missed Status Tracking	Visit Plan	This property configures whether or not Missed status is automatically tracked in the Subject Status MVG (multi value group) for status tracking visits. You configure the status tracking visit for each visit type in the subject visit template. Configure this property as follows: • To enable automatic tracking of Missed status for status tracking visits, set the value to Y. • To disable automatic tracking of Missed status for status tracking visits, set the value to N. The default value is **`Y`**.
Completed Status Code	Visit Plan	This property configures automatic status tracking. The default value follows is **`Completed`**. **Note:** Do not change this value.
Date RollUp Fields:Protocol n	Clinical Protocol Site	This property configures automatic rollup of the Last Subject Off Study date from the site record to the protocol record. The value takes the following parameters: **`"<Source BC Field Name>", "<Target BC Field Name>", "<Sort Order>"`**

User Property	Business Component	Description
		The value is set as follows: `"Last Subject Off Study Date", "Last Subject Off StudyDate", "(DESCENDING)"` **Note:** Do not change this value.

Date RollUp Fields:Region n	Clinical Protocol Site	This property configures automatic rollup of the Last Subject Off Study date from the site record to the region record.
		
		The value takes the following parameters:
		
		`"<Source BC Field Name>", "<Target BC Field Name>", "<Sort Order>"`
		
		The value is set as follows:
		
		`"Last Subject Off Study Date", "Last Subject Off Study Date", "(DESCENDING)"`
		
		Note: Do not change this value.

Delete NonApp WorkFlow Process Name	LS Subject Schedule Date VBC	This property defines the workflow process that is invoked when the Enroll Screen Rescreen Through WorkFlow property is set to Y, and when the Disable Delete Non App Visit property is set to N. The default value is `LS Clinical - DeleteNonAppVisits Process.` If the user clicks OK on the pop-up message that the Disable Delete Non App Visit property enables, then LS Clinical - DeleteNonAppVisits Process is invoked to delete incomplete clinical visits in the previous version of a subject visit template.
Disable Delete Non App Visit	Clinical Subject	This property turns on or off deletion of non applicable clinical subject visits. When users schedule clinical subject visits using a revised subject visit template, a pop-up message appears to confirm if incomplete visits in the previous template version must be deleted, and if complete visits in the new template version must be deleted. Clicking OK in the pop-up message deletes the non applicable subject visits. Clicking Cancel retains the non applicable subject visits. Configure the value as follows: • To enable deletion of non applicable subject visits, set the value to N. • To disable deletion of non applicable subject visits, set the value to Y. The default value is `N`.
Enroll Screen Rescreen Through WorkFlow	LS Subject Schedule Date VBC	This property specifies whether subject visit scheduling tasks are executed through workflows or business component methods. Configure the value as follows: • To execute subject visit scheduling tasks through workflows, set the value to Y. • To execute subject visit scheduling tasks through business component methods, set the value to N. The default value is `N`.

User Property	Business Component	Description
		You configure the workflows that execute the scheduling tasks in the following business component properties: • WorkFlow Process Name • Apply Templates WorkFlow Process Name • Delete NonApp WorkFlow Process Name
Last Subject Off Study Date Rollup Status n	Clinical Protocol Site	This property identifies the qualified subject statuses that are used to populate the date in the Last Subject Off Study field. By default the following statuses are set: • Completed • Early Terminated

LS Amount Rollup Field 1	Clinical Payments	This property configures automatic rollup of Amount Paid To Date from the payment record to the site record.
		The value takes the following parameters:
		`"<Source BC Field Name>", "<Target BC Field Name>", "<Rollup Parent Buscomp Name>"`
		The value is set as follows:
		`"Amount Paid To Date", "Amount Paid To Date", "Rollup Parent Buscomp Name"`
		Note: Do not change this value.

LS Amount Rollup Field 2	Clinical Payments	This property configures automatic rollup of Amount Earned To Date from the payment record to the site record.
		The value takes the following parameters:
		`"<Source BC Field Name>", "<Target BC Field Name>", "<Rollup Parent Buscomp Name>"`
		The value is set as follows:
		`"Amount Earned To Date", "Amount Earned To Date", "Rollup Parent Buscomp Name"`
		Note: Do not change this value.

LS Amount Rollup Field 3	Clinical Payments	This property configures automatic rollup of VAT amounts from the payment record to the site record.
		The value takes the following parameters:
		`"<Source BC Field Name>", "<Target BC Field Name>", "<Rollup Parent Buscomp Name>"`
		The value is set as follows:
		`"VAT Amount", "VAT Amount", "Rollup Parent Buscomp Name"`

User Property	Business Component	Description
		Note: Do not change this value.

LS Amount Rollup Field 3	Clinical Protocol Site	This property configures automatic rollup of VAT amounts from the site record to the region record.
		The value takes the following parameters:
		`"<Source BC Field Name>", "<Target BC Field Name>", "<Rollup Parent Buscomp Name>"`
		The value is set as follows:
		`"VAT Amount", "VAT Amount", "Rollup Parent Buscomp Name"`
		Note: Do not change this value.

LS Amount Rollup Field 3	Clinical Region	This property configures automatic rollup of VAT amounts from the region record to the clinical protocol record.
		The value takes the following parameters:
		`"<Source BC Field Name>", "<Target BC Field Name>", "<Rollup Parent Buscomp Name>"`
		The value is set as follows:
		`"VAT Amount", "VAT Amount", "Rollup Parent Buscomp Name"`
		Note: Do not change this value.

LS Amount Rollup Field 3	Clinical Protocol	This property configures automatic rollup of VAT amounts from the protocol record to the program record.
		The value takes the following parameters:
		`"<Source BC Field Name>", "<Target BC Field Name>", "<Rollup Parent Buscomp Name>"`
		The value is set as follows:
		`"VAT Amount", "VAT Amount", "Rollup Parent Buscomp Name"`
		Note: Do not change this value.

LS Amount Rollup On Status 1	Clinical Payments	This property defines the payment status values that are used to calculate the Paid to Date amount. By default, only payments with a status of Paid are used to calculate the Paid to Date amount. This property takes a comma delimited list of values as follows:

User Property	Business Component	Description
		`"Amount Paid to Date","Paid"`
LS Clinical Enable Revert On Status	Clinical Payments	This property defines the payment status values for which the Revert button is enabled. The value takes a comma delimited list of payment statuses as follows: `"<Status1>", "<Status2>"` By default, the Revert button is enabled for the following payment Status values: • In Progress • To Be Processed
LS Subject Terminate Study Status Value 1	Clinical Subject Status	This property turns on or off the deletion of incomplete future visits for a subject. These incomplete visits are visits for which the date associated with the subject status has a value, the Completed field for the visit is not selected, and the date in the Date field of the visit is later than the date associated with the subject status. When enabled, the incomplete future visits are deleted if the status of the subject is a value in this property. By default, this property includes the following values: • Screen Failure • Early Terminated
Missed Status Code	Visit Plan	This property configures automatic status tracking. The value is set to Missed. **Note:** Do not change this value.
Named Method 1	Action (No Owner Lock)	This property generates payment records. The value string is set as follows: `"GenerateNewPayment", "INVOKESVC", "Action(No Owner Lock)", "LS SubjectVisits Service", "GeneratePayment", "'Site Id'", "[Protocol Site Id]", "'srcBusComp'", "'Action (No Owner Lock)'", "'srcBusObj'", "'Clinical Protocol Site'", "'tgtBusObj'", "'Clinical Payments'", "'tgtBusComp'", "'Clinical Payments'"` **Note:** Do not change this value.
Named Method 1	LS Clinical Subject Status Snapshot	This property generates the subject status snapshot for a clinical site. The value string is set as follows: `"SiteSnap", "INVOKESVC", "LS Clinical Subject Status Snapshot", "LS Clinical Trip Report Svc", "GetSiteSnapshot", '"SVId"', "ParentFieldValue('Id')"`

User Property	Business Component	Description
		Note: Do not change this value.

Named Method 2	Clinical Trip Report	This property turns on or off approver verification for trip reports. When enabled, the User Verification screen is launched during the approval process for trip reports to verify the user logon credentials of the approver.
		
		Configure the value as follows:
		
		• To enable this property, set the value as follows:
		
		`"ValidateUser", "INVOKESVCSEL", "Clinical Trip Report", "Workflow Process Manager", "RunProcess", "ProcessName", "LS Clinical Trip Report Approval", "RowId", "[Id]", "Enable Verification", "Y"`
		
		• To disable this property, set the value as follows:
		
		`"ValidateUser", "INVOKESVCSEL", "Clinical Trip Report", "Workflow Process Manager", "RunProcess", "ProcessName", "LS Clinical Trip Report Approval", "RowId", "[Id]", "Enable Verification", "N"`
		
		This property is disabled by default, and cannot be null.
		
		Note: Customers who do not have a license for Siebel Tools can use the CL – Verify TripReportApprover system preference to configure this functionality. For more information about configuring system preferences, see *System Preferences in Siebel Clinical*.

Named Method n	Clinical Protocol Site for Popup	This property associates accounts, activities, and documents for clinical protocols and clinical regions with sites. It specifies the method (for example, ProtocolAccountRolldownToSite) for the appropriate popup applet, the underlying business component (Clinical Protocol Site for Popup) for that applet, the method (ApplyRolldown) in that business component that calls the rolldown business service (LS Clinical Record Rolldown Service), and the appropriate user property (for example, Protocol Account To Site Rolldown) as the input argument for the business service.
		
		To associate accounts for clinical protocols with sites, set the value string as follows:
		
		`"ProtocolAccountRolldownToSite", "INVOKESVC", "Clinical Protocol Site for Popup", "LS Clinical Record Rolldown Service", "ApplyRolldown", "UserPropertyName", "Protocol Account To Site Rolldown"`
		
		To associate accounts for clinical regions with sites, set the value string as follows:
		
		`"RegionAccountRolldownToSite", "INVOKESVC", "Clinical Protocol Site for Popup", "LS Clinical Record Rolldown Service", "ApplyRolldown", "UserPropertyName", "Region Account To Site Rolldown"`
		
		To associate activities for clinical protocols with sites, set the value string as follows:

User Property	Business Component	Description

		`"ProtocolActivityRolldownToSite", "INVOKESVC", "Clinical Protocol Site for Popup", "LS Clinical Record Rolldown Service", "ApplyRolldown", "UserPropertyName", "Protocol Activity To Site Rolldown"`
		To associate activities for clinical regions with sites, set the value string as follows:
		`"RegionActivityRolldownToSite", "INVOKESVC", "Clinical Protocol Site for Popup", "LS Clinical Record Rolldown Service", "ApplyRolldown", "UserPropertyName", "Region Activity To Site Rolldown"`
		To associate documents for clinical protocols with sites, set the value string as follows:
		`"ProtocolDocumentRolldownToSite", "INVOKESVC", "Clinical Protocol Site for Popup", "LS Clinical Record Rolldown Service", "ApplyRolldown", "UserPropertyName", "Protocol Document To Site Rolldown"`
		To associate documents for clinical regions with sites, set the value string as follows:
		`"RegionDocumentRolldownToSite", "INVOKESVC", "Clinical Protocol Site for Popup", "LS Clinical Record Rolldown Service", "ApplyRolldown", "UserPropertyName", "Region Document To Site Rolldown"`

Status Field RollUp n	Clinical Subject Status	This property collates subject numbers for each status value. You can also configure it to collate subjects status and visit type value pairs. The subject accruals data is rolled up to the site record. The following comma-delimited parameter configurations are supported: • `"[Subject Status]", "[Business Component Field Name]", "[Visit Type]"` • `"[Subject Status]", "[Business Component Field Name]", "[Null]"` • `"[Subject Status]", "[Business Component Field Name]"` The Subject Status and Business Component Field Name parameters are mandatory. The Visit Type parameter is optional. The Visit Type value is not populated by default. The following example provides the default configuration for the Enrolled status, and collates the subjects with an Enrolled status for automatic rollup to the site record: `"Enrolled", "# Enrolled"`
Status RollUp Fields:Protocol n	Clinical Protocol Site	This property collates subject numbers for each status value. You can also configure it to collate subjects status and visit type value pairs. The subject accruals data is rolled up to the protocol record. The following comma-delimited parameter configurations are supported:

User Property	Business Component	Description
		• `"[Subject Status]", "[Business Component Field Name]", "[Visit Type]"` • `"[Subject Status]", "[Business Component Field Name]", "[Null]"` • `"[Subject Status]", "[Business Component Field Name]"` The Subject Status and Business Component Field Name parameters are mandatory. The Visit Type parameter is optional. The Visit Type value is not populated by default. The following example provides the default configuration for the Enrolled status, and collates the subjects with an Enrolled status for automatic rollup to the protocol record: `"Enrolled", "# Enrolled"`
Status RollUp Fields:Region n	Clinical Protocol Site	This property collates subject numbers for each status value. You can also configure it to collate subject status and visit type value pairs. The subject accruals data is rolled up to the region record. The following comma-delimited parameter configurations are supported: • `"[Subject Status]", "[Business Component Field Name]"` • `"[Subject Status]", "[Business Component Field Name]", "[Visit Type]"` • `"[Subject Status]", "[Business Component Field Name]", "[Null]"` The Subject Status and Business Component Field Name parameters are mandatory. The Visit Type parameter is optional. The Visit Type value is not populated by default. The following example provides the default configuration for the Enrolled status, and collates the subjects with an Enrolled status for automatic rollup to the region record: `"Enrolled", "# Enrolled"`
Status Tracking Field n	Clinical Subject	This property configures automatic status tracking for subject status. By, default, automatic subject status tracking applies to fields related to the following subject statuses: • Screen Failure • Randomized • Withdrawn • Early Terminated You can track additional custom subject statuses by configuring additional values for this property type. This property takes the following comma-delimited list of parameters: `"[Business Component Field Name]", "[DateField]", "[Status Value"` • `[Business Component Field Name]` is the name of the business component field that is tracked for automatic status tracking, for example, Randomization ID.

User Property	Business Component	Description
		• `[Date Field]` is the name of the corresponding date field that is tracked for automatic status tracking, for example, Randomized Date. • `[Status Value]` is the corresponding status value that is tracked for automatic status tracking, for example, Randomized.
Status Tracking Field 1	Clinical Subject	This property configures automatic status tracking for the subject status of Randomized. The default value follows: `"Randomization Id", "Randomized Date", "Randomized"` To track additional custom subject statuses, see Status Tracking Field n.
Status Tracking Field 2	Clinical Subject	This property configures automatic status tracking for the subject status of Screen Failure. The default value follows: `"Reason Excluded", "Screen Failure Date", "Screen Failure"` To track additional custom subject statuses, see Status Tracking Field n.
Status Tracking Field 3	Clinical Subject	This property configures automatic status tracking for the subject status of Withdrawn. The default value follows: `"Withdrawn Reason", "Withdrawn Date", "Withdrawn"` To track additional custom subject statuses, see Status Tracking Field n.
Status Tracking Field 4	Clinical Subject	This property configures automatic status tracking for the subject status of Early Terminated. The default value follows: `"Early Termination Reason", "Early Terminated Date", "Early Terminated"` To track additional custom subject statuses, see Status Tracking Field n.
Trip Report Template Filter 1	Clinical Trip Report	This property filters the trip report templates in the dialog box that appears when users click the select button in the Template field of a Trip Report form. It designates that templates with a protocol that is the same as the protocol for the site visit appear in the dialog box. Templates with no protocol also appear in the dialog box. The default value follows: `"Protocol Id", "Protocol Id"` The first value designates the field name for protocols in the Clinical Trip Report business component. The second value designates the field name for protocols in the LS Clinical Trip Report Template business component.
Trip Report Template Filter 2	Clinical Trip Report	This property filters the trip report templates in the dialog box that appears when users click the select button in the Template field of a Trip Report form. It designates

User Property	Business Component	Description
		that templates with a region that is the same as the region for the site visit appear in the dialog box. Templates with no region also appear in the dialog box. The default value follows: `"Region Id", "Region Id"` The first value designates the field name for regions in the Clinical Trip Report business component. The second value designates the field name for regions in the LS Clinical Trip Report Template business component.
Trip Report Template Filter 3	Clinical Trip Report	This property filters the trip report templates in the dialog box that appears when users click the select button in the Template field of a Trip Report form. It designates that templates with a visit type that is the same as the visit type for the site visit appear in the dialog box. Templates with no visit type also appear in the dialog box. The default value follows: `"Type", "Visit Type"` The first value designates the field name for visit types in the Clinical Trip Report business component. The second value designates the field name for visit types in the LS Clinical Trip Report Template business component.
Validate Field	LS Subject Enrollment Date VBC	**Note:** This property is deprecated in version 8.1.1.9 and later. This property represents the name of the field to validate. The default value is Enrollment ID.

Validate On 1	Clinical Trip Report	This property turns on or off validation for trip reports that have a status of Rejected.
		
		When enabled, trip reports that have a status of Rejected are validated to ensure that one of the following fields is populated:
		
		• Reviewer Comments
		• Approver Comments
		Configure the value as follows:
		
		• To enable this property, set the value as follows:
		
		`"Rejected", "Y"`
		
		• To disable this property, set the value as follows:
		
		`"Rejected", "N"`
		
		This property is enabled by default.

Validate On 2	Clinical Trip Report	This property turns on or off validation for trip reports that have a status of Submitted. When enabled, trip reports that have a status of Submitted are validated to ensure that a reviewer is assigned to the trip report. Configure the value as follows:

User Property	Business Component	Description

		• To enable this property, set the value as follows:
		`"Submitted", "Y"`
		• To disable this property, set the value as follows:
		`"Submitted", "N"`
		This property is enabled by default.

Validate On 3	Clinical Trip Report	This property turns on or off validation for trip reports that have a status of Submitted for Approval.
		When enabled, trip reports that have a status of Submitted for Approval are validated to ensure that an approver is assigned to the trip report.
		Configure the value as follows:
		• To enable this property, set the value as follows:
		`"Submitted for Approval", "Y"`
		• To disable this property, set the value as follows:
		`"Submitted for Approval", "N"`
		This property is enabled by default.

WorkFlow Process Name	LS Subject Schedule Date VBC	This property defines the workflow process that is invoked when the Enroll Screen Rescreen Through WorkFlow property is set to Y. The default value is `LS Clinical - SubjectVisits Process`. This workflow process applies the approved subject visit template to the subject. If the subject visit template that is applied is different from the previous version of the subject visit template that was applied, and if the Disable Delete Non App Visit property is set to N, then a pop-up message appears to confirm if incomplete visits in the previous template version must be deleted, and if complete visits in the new template version must be deleted. Clicking OK in the pop-up message deletes the non applicable subject visits. Clicking Cancel retains the non applicable subject visits.

User Properties for Business Services in Siebel Clinical

The following table describes the business service user properties that you can use to enable and configure functionality for Siebel Clinical.

User Property	Business Service	Project	Description
Data Rollup Is On	LS Data Rollup	LS Clinical Enhancement	This property configures rollup of subject status data to sites, regions, and protocols.

User Property	Business Service	Project	Description
			Configure the value as follows: • To enable this property, set the value to Y. • To disable this property, set the value to N. This property is enabled by default.
Protocol Account To Site Rolldown	LS Clinical Record Rolldown Service	LS Clinical Admin	This property associates accounts for clinical protocols with sites. It specifies the data map information in the form of an input argument for the business service method. The named method property for the underlying business component calls this business service when you click the OK button in the LS Clinical Protocol Account Site Popup applet. This applet appears when you click the Apply To Sites button in the Accounts view of the Protocols screen. The default value for this property follows: `'LS Clinical Protocol Account To Sites', 'LS Clinical Account', 'Id', 'Clinical Protocol Site for Popup', 'Id'` In this value, LS Clinical Protocol Account To Sites is a data map that maps the fields in accounts for protocols to the fields in accounts for sites, LS Clinical Account is the name of the source business component, and Clinical Protocol Site for Popup is the name of the underlying business component for the LS Clinical Protocol Account Site Popup applet. Id is a field that uniquely identifies an account in the source business component and a site in the business component for the popup applet. You can change the field mapping for data maps in the Data Component list in the Data Map Administration view of the Administration - Application screen. For more information about changing data maps, see *Siebel Order Management Infrastructure Guide* .
Protocol Activity To Site Rolldown	LS Clinical Record Rolldown Service	LS Clinical Admin	This property associates activities for clinical protocols with sites. It specifies the data map information in the form of an input argument for the business service method. The named method property for the underlying business component calls this business service when you click the OK button in the LS Clinical Protocol Activity Site Popup applet. This applet appears when you click the Apply To Sites button in the Activities view of the Protocols screen. The default value for this property follows: `'LS Clinical Protocol Activity To Sites', 'LS Action(Protocol/Region)', 'Id', 'Clinical Protocol Site for Popup', 'Id'` In this value, LS Clinical Protocol Activity To Sites is a data map that maps the fields in activities for protocols to the fields in activities for sites, LS Action (Protocol/Region) is the name of the source business component, and Clinical Protocol Site for Popup is the name of underlying business component for the LS Clinical Protocol Activity Site Popup applet. Id is a field that uniquely identifies an activity in

User Property	Business Service	Project	Description
			the source business component and a site in the business component for the popup applet. You can change the field mapping for data maps in the Data Component list in the Data Map Administration view of the Administration - Application screen. For more information about changing data maps, see *Siebel Order Management Infrastructure Guide* .
Protocol Document To Site Rolldown	LS Clinical Record Rolldown Service	LS Clinical Admin	This property associates documents for clinical protocols with sites. It specifies the data map information in the form of an input argument for the business service method. The named method property for the underlying business component calls this business service when you click the OK button in the LS Clinical Protocol Document Site Popup applet. This applet appears when you click the Apply To Sites button in the Document Tracking view of the Protocols screen. The default value for this property follows: `'LS Clinical Protocol Document To Sites', 'LS Document Tracking', 'Id', 'Clinical Protocol Site for Popup', 'Id'` In this value, LS Clinical Protocol Document To Sites is a data map that maps the fields in documents for protocols to the fields in documents for sites, LS Document Tracking is the name of the source business component, and Clinical Protocol Site for Popup is the name of underlying business component for the LS Clinical Protocol Document Site Popup applet. Id is a field that uniquely identifies a document in the source business component and a site in the business component for the popup applet. You can change the field mapping for data maps in the Data Component list in the Data Map Administration view of the Administration - Application screen. For more information about changing data maps, see *Siebel Order Management Infrastructure Guide* .
Region Account To Site Rolldown	LS Clinical Record Rolldown Service	LS Clinical Admin	This property associates accounts for clinical regions with sites. It specifies the data map information in the form of an input argument for the business service method. The named method property for the underlying business component calls this business service when you click the OK button in the LS Clinical Region Account Site Popup applet. This applet appears when you click the Apply To Sites button in the Accounts view of the Regions screen. The default value for this property follows: `'LS Clinical Region Account To Sites', 'LS Clinical Account', 'Id', 'Clinical Protocol Site for Popup', 'Id'` In this value, LS Clinical Region Account To Sites is a data map that maps the fields in accounts for regions to the fields in accounts for sites, LS Clinical Account is the name of the source business component, and Clinical Protocol Site for Popup is the name of the underlying business component for the LS Clinical Region Account Site Popup

User Property	Business Service	Project	Description
			applet. Id is a field that uniquely identifies an account in the source business component and a site in the business component for the popup applet. You can change the field mapping for data maps in the Data Component list in the Data Map Administration view of the Administration - Application screen. For more information about changing data maps, see *Siebel Order Management Infrastructure Guide* .
Region Activity To Site Rolldown	LS Clinical Record Rolldown Service	LS Clinical Admin	This property associates activities for clinical regions with sites. It specifies the data map information in the form of an input argument for the business service method. The named method property for the underlying business component calls this business service when you click the OK button in the LS Clinical Region Activity Site Popup applet. This applet appears when you click the Apply To Sites button in the Activities view of the Regions screen. The default value for this property follows: `'LS Clinical Region Activity To Sites', 'LS Action(Protocol/Region)', 'Id', 'Clinical Protocol Site for Popup', 'Id'` In this value, LS Clinical Region Activity To Sites is a data map that maps the fields in activities for regions to the fields in activities for sites, LS Action (Protocol/Region) is the name of the source business component, and Clinical Protocol Site for Popup is the name of the underlying business component for the LS Clinical Region Activity Site Popup applet. Id is a field that uniquely identifies an activity in the source business component and a site in the business component for the popup applet. You can change the field mapping for data maps in the Data Component list in the Data Map Administration view of the Administration - Application screen. For more information about changing data maps, see *Siebel Order Management Infrastructure Guide* .
Region Document To Site Rolldown	LS Clinical Record Rolldown Service	LS Clinical Admin	This property associates documents for clinical regions with sites. It specifies the data map information in the form of an input argument for the business service method. The named method property for the underlying business component calls this business service when you click the OK button in the LS Clinical Region Document Site Popup applet. This applet appears when you click the Apply To Sites button in the Document Tracking view of the Region screen. The default value for this property follows: `'LS Clinical Region Document To Sites', 'LS Document Tracking', 'Id', 'Clinical Protocol Site for Popup', 'Id'` In this value, LS Clinical Region Document To Sites is a data map that maps the fields in documents for regions to the fields in documents for sites, LS Document Tracking is the name of the source business component, and Clinical Protocol Site for Popup is the name of the underlying

User Property	Business Service	Project	Description
			business component for the LS Clinical Region Document Site Popup applet. Id is a field that uniquely identifies a document in the source business component and a site in the business component for the popup applet. You can change the field mapping for data maps in the Data Component list in the Data Map Administration view of the Administration - Application screen. For more information about changing data maps, see *Siebel Order Management Infrastructure Guide* .

You can configure additional properties for the LS Clinical Record Rolldown Service business service to set up additional functionality for rolldowns. An example of such a custom property follows:

```
'Custom Data Map', 'Source Business Component', 'Id', 'Business Component for the
Popup Applet', 'Id'
```

In this value, Custom Data Map is a data map that maps the fields in the source business component to the fields in the target business component, Id is a field that uniquely identifies a record in the source business component and a record in the underlying business component for the popup applet. The named method property for the underlying business component calls this business service when you click the OK button in the appropriate popup applet.

The value for the named method property specifies the method for the appropriate popup applet, the underlying business component for that applet, the method in that business component that calls the rolldown business service, and the appropriate user property as the input argument for the business service. An example of such a custom property follows:

```
"CustomAppletMethod", "INVOKESVC", "Business Component for the Popup Applet", "LS
Clinical Record Rolldown Service", "ApplyRolldown", "UserPropertyName",
"CustomProperty"
```

Applet Properties in Siebel Clinical

The following table describes the applet properties that you can use to enable and configure functionality for Siebel Clinical.

Property	Applet	Description
ClosePopUp	LS Clinical Protocol Account Site Popup Applet LS Clinical Protocol Activity Site Popup Applet LS Clinical Protocol Document Site Popup Applet LS Clinical Region Account Site Popup Applet LS Clinical Region Activity Site Popup Applet	This property closes the pop-up applet when an end user performs an action to close this applet, such as clicking the OK button. This action calls the method in the value for this property. You can enter a comma-delimited list in this property to specify multiple methods. An example follows: `ClosePopUp="method 1", "method 2", "method 3"` The default value (method name) for each of the six applets follows: • ProtocolAccountRolldownToSite • ProtocolActivityRolldownToSite

Property	Applet	Description
	LS Clinical Region Document Site Popup Applet	• ProtocolDocumentRolldownToSite • RegionAccountRolldownToSite • RegionActivityRolldownToSite • RegionDocumentRolldownToSite You can use this property in applets that are associated with the CSSSWEFrRolePopup class.
HideInQueryMode	Any applet that uses one of the following classes or a class derived from these classes: CSSSWEClinicalList Base CSSSWEClinicalForm Base	This property hides the buttons that call the methods in this property. This property hides these buttons when end users click Query in the applet. You can enter a comma-delimited list in this property to specify multiple methods. An example follows: `HideInQueryMode="ShowAll", "ShowCurrent", "CallCustomerMaster"` If the button calls the ShowPopup method, you do not have to include that method in this property.
History Target BC (Internal)	Clinical Protocol Team Mvg Applet Clinical Region Team Mvg Applet	This property specifies the target business component. The default values follow: • Clinical Protocol Site Team Assignment History BC • Clinical Protocol Team Assignment History BC • Clinical Region Team Assignment History BC The information about the positions added to or deleted from the team list is added to the specified business component.

Search Specification	Clinical Protocol Site Template Version Assoc Applet	This property configures the versions of the subject visit template that appear in the Site Management Versions MVG (multi value group).
		Configure this property as follows:
		• To display only the versions of the subject visit templates with a status of Approved, set the value as follows:
		`[Status Cd] = LookupValue("CLNCL_VERSION_STATUS","Approved")`
		• To display the versions of the subject visit templates with a status of Reviewed or Approved, set the value as follows:
		`[Status Cd] = LookupValue("CLNCL_VERSION_STATUS","Approved") OR [Status Cd] = LookupValue("CLNCL_VERSION_STATUS","Reviewed")`
		The default configuration displays only subject visit templates with a status of Approved in the Site Management Versions MVG.

Popup Visibility Type	LS Clinical Site Bulk Payment Popup Applet	This property determines the site records that appear in the dialog box that appears when end users click the Generate Payment

Property	Applet	Description
		button in the Payments view of the Protocols screen or the Regions screen. The default value for this property is All. This value means that all site records in the Siebel Clinical application appear in the dialog box. This property can have the following alternate values, which are standard Siebel view modes: • Personal • Sales Rep • Manager • Organization • Sub-Organization • Group • Catalog View modes determine the records that end users can see in a view that is associated with an underlying business component. For example, if you set this property value to Organization, then the end user who clicks the Generate button can see the site records for the protocol or region that are associated with the organization of the end user. This property overrides the pop-up visibility of the underlying business component. The underlying business component must support the view mode associated with the value that you enter. For more information about view modes, see *Siebel Security Guide* .
WF.Abstract	LS Clinical Site Bulk Payment Popup Applet	This property configures notifications for bulk payments by specifying the value for the Abstract field that is passed as an input argument to the workflow that the GenerateBulkPayment method calls when you click the OK button in the LS Clinical Site Bulk Payment Applet. This applet appears when you click the Generate Payment button in the Payments view of the Protocols screen or the Regions screen. The input argument is a key-value combination. An example follows: `Abstract="Bulk payment status update"` This example shows the default value for this property, but you can change this value.
WF.AllowDismiss	LS Clinical Site Bulk Payment Popup Applet	This property configures notifications for bulk payments by specifying the value for the AllowDismiss field that is passed as an input argument to the workflow that the GenerateBulkPayment method calls when you click the OK button in the LS Clinical Site Bulk Payment Applet. This applet appears when you click the Generate Payment button in the Payments view of the Protocols screen or the Regions screen. The input argument is a key-value combination. An example follows: `AllowDismiss="Y"`

Property	Applet	Description
		This example shows the default value for this property, but you can change this value.
WF.AllUsers	LS Clinical Site Bulk Payment Popup Applet	This property configures notifications for bulk payments by specifying the value for the AllUsers field that is passed as an input argument to the workflow that the GenerateBulkPayment method calls when you click the OK button in the LS Clinical Site Bulk Payment Applet. This applet appears when you click the Generate Payment button in the Payments view of the Protocols screen or the Regions screen. The input argument is a key-value combination. An example follows: `AllUsers="N"` This example shows the default value for this property, but you can change this value.
WF.ListOfRecipient Divisions	LS Clinical Site Bulk Payment Popup Applet	This property configures notifications for bulk payments by specifying the values for the Recipient Division field that are passed as an input argument to the workflow that the GenerateBulkPayment method calls when you click the OK button in the LS Clinical Site Bulk Payment Applet. This applet appears when you click the Generate Payment button in the Payments view of the Protocols screen or the Regions screen. When a value in the Recipient Division field of the notification message matches a value in the Division field of a team record for a site, the end users associated with that division receive notifications of payments to that site. For information about setting up notification messages, see *Siebel Applications Administration Guide* . The default value for this property is DivisionName(), but you can change this value. The value for this property is a Siebel grammar expression that is similar to the expressions in calculated fields for business components. Because the destination field for this property is an MVG (multi value group), you can enter a comma-delimited list in this property to specify multiple values. An example follows: `"DivisionName()", "Home Office Division"` You can activate this property if necessary.
WF.ListOfRecipient Positions	LS Clinical Site Bulk Payment Popup Applet	This property configures notifications for bulk payments by specifying the values for the Recipient Position field that are passed as an input argument to the workflow that the GenerateBulkPayment method calls when you click the OK button in the LS Clinical Site Bulk Payment Applet. This applet appears when you click the Generate Payment button in the Payments view of the Protocols screen or the Regions screen. When a value in the Recipient Position field of the notification message matches a value in the Position field of a team record for a site, the end users associated with that position receive notifications of payments to that site. For information about setting

Property	Applet	Description
		up notification messages, see *Siebel Applications Administration Guide* . The default value for this property is PositionName(), but you can change this value. The value for this property is a Siebel grammar expression that is similar to the expressions in calculated fields for business components. Because the destination field for this property is an MVG (multi value group), you can enter a comma-delimited list in this property to specify multiple values. An example follows: `"PositionName()", "HQ - US Region"` You can activate this property if necessary.
WF.ListOfRecipientUsers	LS Clinical Site Bulk Payment Popup Applet	This property configures notifications for bulk payments by specifying the values for the Recipient User field that are passed as an input argument to the workflow that the GenerateBulkPayment method calls when you click the OK button in the LS Clinical Site Bulk Payment Applet. This applet appears when you click the Generate Payment button in the Payments view of the Protocols screen or the Regions screen. When a value in the Recipient User field of the notification message matches a value in the User ID field of a team record for a site, the end user associated with that user ID receives notifications of payments to that site. For information about setting up notification messages, see *Siebel Applications Administration Guide* . The default value for this property is LoginName(), but you can change this value. The value for this property is a Siebel grammar expression that is similar to the expressions in calculated fields for business components. Because the destination field for this property is an MVG (multi value group), you can enter a comma-delimited list in this property to specify multiple values. An example follows: `"LoginName()", "JDOE"`
WF.ProcessName	LS Clinical Site Bulk Payment Popup Applet	This property specifies the name of the underlying workflow that the GenerateBulkPayment method calls when you click the OK button in the LS Clinical Site Bulk Payment Applet. This applet appears when you click the Generate Payment button in the Payments view of the Protocols screen or the Regions screen. Notification-related arguments (WF.Abstract, WF.AllowDismiss, and so on) are then passed as input arguments (Abstract, AllowDismiss, and so on) to this workflow. The default value for this property is LS Clinical - Generate Bulk Payment Process, but you can change this value to a custom workflow.
WF.Severity	LS Clinical Site Bulk Payment Popup Applet	This property configures notifications for bulk payments by specifying the value for the Severity field that is passed as an input argument to the workflow that the GenerateBulkPayment method calls when you click the OK button in the LS Clinical Site Bulk Payment Applet. This applet appears when you click the Generate

Property	Applet	Description
		Payment button in the Payments view of the Protocols screen or the Regions screen. The input argument is a key-value combination. An example follows: `Severity="Normal"` This example shows the default value for this property, but you can change this value to any value for the Severity field that has a Type field value of BRDCST_MSG_TYPE in the list of values and that is active in the list of values. Alternate values include: High, Urgent, and Urgent with Alert.

For applets that are associated with the CSSSWEFrRolePopup class and that have Clinical Protocol Site Bulk Operations as the underlying business component, you can create additional input arguments for the workflow that the GenerateBulkPayment method calls by creating additional applet properties as `WF.field name` , and recompiling the applet. For example, a custom property of WF.CustomerName might have the following input argument for the workflow:

```
CustomerName="Elixir Labs"
```

Field Properties in Siebel Clinical

The following information lists the field properties that you can use to enable and configure functionality for Siebel Clinical.

Property	Parent Field	Description
Append All Activities	Enrollment Date Screen Date Rescreen Date	**Note:** This property is deprecated in version 8.1.1.9 and later. This property configures whether or not users can copy the activities in the subject visit template multiple times. Configure this property as follows: • Set the value to Y to allow users to copy the activities in the subject visit template multiple times. • Set the value to N to disallow users to copy the activities in the subject visit template multiple times. The default property value for each parent field follows: Enrollment Date = N Screen Date = N Rescreen Date = Y
Subject Consent Required	Screen Date	This property configures whether or not subject informed consent is mandatory when scheduling a clinical subject. When enabled, the

Property	Parent Field	Description
		Informed Consent Date field is checked for data when the user clicks Schedule. Configure this property as follows: • To set the Informed Consent Date as a mandatory field when scheduling a clinical subject, set the value to Y. • To set the Informed Consent Date as an optional field when scheduling a clinical subject, set the value to N. The default value is N.
Template Type Code]	Enrollment Date Screen Date Rescreen Date	**Note:** This property is deprecated in version 8.1.1.9 and later. This property configures the subject visit template type that is used when applying a template. The default property value for each parent field follows: Enrollment Date = 'Enrollment' Screen Date = 'Screening' Rescreen Date ='Re-Screening'

System Preferences in Siebel Clinical

The following information lists the system preferences that you can use to configure core functionality in Siebel Clinical Trial Management System and to integrate Siebel Clinical Trial Management System with third-party applications.

System Preference	Functionality
CL Highest Preference SDV Rule	This setting determines the priority order in which to implement the 3 methods (Manual, Site, and Status) to change the SDV Required field of a subject record. Valid values for this system preference are Status and Manual. The default value is Status. To understand the priority order for each value in this system preference, note the following scenario: • Site method: The Subject Auto-Select Rate field for the site associated with the subject is 50%. Thus, every other subject record initially has a SDV Required field of Yes. • Status method: A status rule set indicates that if the Status field of a subject record is Early Terminated, then the SDV Required field of the subject record is automatically changed to Yes. None of the Status fields in the subject records initially has a value of Early Terminated. If you set this system preference to Status, then the 3 methods are implemented in the following priority order: Status, Manual, and Site. Note the following: • You can manually change the SDV Required field of a subject record from Yes to No because the manual method has a higher priority than the sitee method.

System Preference	Functionality
	• If you change the Status field of the subject record to Early Terminated, then the SDV Required field of the subject record automatically changes back to Yes because the status method has a higher priority than the manual method. • You cannot manually change the SDV Required field of the subject record back to No because the status method has a higher priority than the manual method. • If you change the value in the Subject Auto-Select Rate field for the site associated with the subject, then the SDV Required field cannot automatically change because the status method has a higher priority than the site method. If you set this system preference to Manual, then the 3 methods are implemented in the following order: Manual, Status, and Site. Note the following: • You can manually change the SDV Required field of a subject record from Yes to No because the manual method has a higher priority than the status method and the site method. • If you change the Status field of the subject record to Early Terminated, then the SDV Required field does not automatically change back to Yes because the manual method has a higher priority than the status method. • If you change the value in the Subject Auto-Select Rate field for the site associated with the subject, then the SDV Required field cannot automatically change because the manual method has a higher priority than the site method.
CL – Verify TripReportApprover	This setting turns on or off approver verification for trip reports. When enabled, the User Verification screen is launched during the approval process for trip reports to verify the user login credentials of the approver. To enable approver verification for trip reports, set the value to Y. The value is set to N by default.
Clinical_Training_Commit_Freq	This setting determines how frequently updated site records are saved in the Siebel database when you run the batch job to publish training plans and associate training topics with the site records. The default value for this system preference is 10. This value indicates that each time 10 site records are updated in the batch job those site records are saved in the Siebel database. If the value for this system preference is 10, if 92 site records must be updated in the batch job, and if a failure occurs during the job run, then the result of the batch job is that the number of site records saved to the Siebel database is a multiple of 10 (for example, 60 site records), and not 0 site records. If you run the batch job again, then only the remaining 32 updated site records are saved in the Siebel database.

Workflows in Siebel Clinical

The following information lists the required workflows for Siebel Clinical core functionality and for integrating Siebel Clinical with third-party applications. For more information about each workflow, see the corresponding functional area in this guide. You can use Siebel Business Process Designer to modify the workflows to suit your own business model. For information about configuring workflows, see *Siebel Business Process Framework: Workflow Guide* .

Workflow Name	Siebel Clinical Functionality
Clinical Assign Position From Protocol	Clinical Protocol

Workflow Name	Siebel Clinical Functionality
Clinical Assign Position From Region Rolldown	Clinical Region
Clinical Assign Position From Region	Clinical Region
Clinical Assign Position From Site Rollup	Clinical Site
Clinical Assign Position From Site	Clinical Site
Clinical Protocol Position History Update	Clinical Protocol
Clinical Region Delete Rollup	Clinical Region
Clinical Region First Site Initiation Date Upsert Rollup	Clinical Region
Clinical Region First Subject Enrolled Date Upsert Rollup	Clinical Region
Clinical Region Last Site Terminated Date Upsert Rollup	Clinical Region
Clinical Region Last Subject Off Study Date Upsert Rollup	Clinical Region
Clinical Region Position History Update	Clinical Region
Clinical Region Status Fields Rollup	Clinical Region
Clinical Remove Position From Protocol	Clinical Protocol
Clinical Remove Position From Region	Clinical Region
Clinical Remove Position From Site	Clinical Site
Clinical Rollup Batch Process	Clinical Site
Clinical Site Delete Rollup to Protocol	Clinical Site
Clinical Site Delete Rollup to Region	Clinical Site
Clinical Site Delete Rollup	Clinical Site

Workflow Name	Siebel Clinical Functionality
Clinical Site First Subject Enrolled Date Upsert Rollup	Clinical Subject
Clinical Site Initiation Completed Date Upsert Rollup	Clinical Site
Clinical Site Last Subject Off Study Date Upsert Rollup	Clinical Site
Clinical Site Position History Update	Clinical Site
Clinical Site Status Fields Rollup	Clinical Site
Clinical Site Termination Date Upsert Rollup (With Subject Info)	Clinical Site
Clinical Site Termination Date Upsert Rollup (Without Subject Info)	Clinical Site
Clinical Status Delete Rollup	Clinical Subject
Clinical Status Upsert Rollup	Clinical Subject
Clinical Subject Delete Rollup	Clinical Subject
LS Clinical - ApplyTemplates Process	Clinical Template
LS Clinical - DeleteNonAppVisits Process	Clinical Subject Visits
LS Clinical - SubjectVisits Process	Clinical Subject Visits
LS Clinical Contract Rollup	Clinical Contract
LS Clinical Create Inbox Item for New Trip Report Owner	Clinical Trip Report
LS Clinical Create Inbox Item for Trip Report Approver	Clinical Trip Report
LS Clinical Create Inbox Item for Trip Report Owner	Clinical Trip Report
LS Clinical Create Inbox Item for Trip Report Reviewer	Clinical Trip Report

Workflow Name	Siebel Clinical Functionality
LS Clinical Earned To Date Rollup	Clinical Payments
LS Clinical - Generate Bulk Payment Process	Clinical Payments
LS Clinical Get Site Snapshot Service	Clinical Trip Report
LS Clinical Set Study Plan Information	Clinical operations integration
LS Clinical Paid To Date Rollup	Clinical Payments
LS Clinical Payment Delete Rollup	Clinical Payments
LS Clinical Payments Outbound	Third-party payments application integration
LS Clinical Protocol Delete Rollup	Clinical Protocol
LS Clinical Protocol Site Get Sites	Clinical Site
LS Clinical Protocol Site Get User Position	Clinical Site
LS Clinical Protocol Training Rollup	Clinical Training
LS Clinical Questions Batch Clean-up	Clinical Trip Report
LS Clinical Region Training Rollup	Clinical Training
LS Clinical Site Accruals Rollup	Clinical Site
LS Clinical Site Subject Delete Accruals Rollup	Clinical Subject
LS Clinical State Validation	Third-party payments application integration
LS Clinical Total Contract Amount Rollup	Clinical operations integration
LS Clinical Training Implementation	Clinical Training
LS Clinical Trip Report Approval	Clinical Trip Report
LS Clinical VAT Amount Rollup	Clinical Payments

Workflow Name	Siebel Clinical Functionality
LS ClinicalProtocolSite Outbound - NewSite	Site visit data integration
LS ClinicalProtocolSite Outbound - UpdatedSite	Clinical Protocol
SWI LS Clinical Create Site Visit Geo Location	Site visit data integration
SWI LS Clinical Payments Inbound	Third-party payments application integration
SWI LS Clinical Query Protocol Site_Site Visits	Site visit data integration
SWI LS Clinical Subject Inbound - Activity	Clinical data management system integration
SWI LS Clinical Subject Inbound - Subject	Clinical data management system integration
SWI LS Clinical Subject Inbound	Clinical data management system integration
SWI - Protocol Number Lookup	Clinical data management system integration

Web Services in Siebel Clinical

You can customize the Web services in Siebel Clinical for integration with any third-party clinical application or for specific business requirements. The following information lists the Web services for mobile and external application integration. For more information about each Web service, see the corresponding integration chapter in this guide. For information about customizing Web services, see *Siebel CRM Web Services Reference* .

Web Service Name	Siebel Clinical Feature
ClinicalSubject	Clinical data capture integration
LS Clinical CRF Tracking Interface	Clinical operations integration
LS Clinical Protocol Site Interface Service	Clinical data capture integration Clinical operations integration
LS Clinical Subject Information Interface Service	Clinical operations integration

Web Service Name	Siebel Clinical Feature
LS Clinical Trip Report File Transfer Web Service	CTMS and eTMF integration
SWI LS Clinical Payments Inbound	Payments application integration
SWILSClinicalActivityTemplate	Mobile integration
SWILSClinicalCreateSiteVisitGeoLocation	Site visit data integration
SWILSClinicalGetEmployees	Mobile integration
SWILSClinicalGetSiteContacts	Mobile integration
SWILSClinicalGetSiteSnapshot	Mobile integration
SWILSClinicalGetSmartScriptDetails	Mobile integration
SWILSClinicalGetStateModelService	Mobile integration
SWILSClinicalGetSubjectVisitDetails	Mobile integration
SWILSClinicalInsertEmployees	Mobile integration
SWILSClinicalListOfValues	Mobile integration
SWILSClinicalProtocolSiteGetSites	Mobile integration
SWILSClinicalQueryProtocolSite_SiteVisits	Site visit data integration
SWILSClinicalSiteContactsTrainingInterface	Training integration
SWILSClinicalTripReportInterfaceService	Mobile integration
SWILSClinicalTripReportTemplates	Mobile integration